

# **EXHIBIT E**

Bobby Lewis Shull, M.D.

Page 1

UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT  
OF WEST VIRGINIA AT CHARLESTON

---

IN RE: ETHICON, INC.,	)	Master File
PELVIC REPAIR SYSTEM	)	2:12-MD-0237
PRODUCTS LIABILITY	)	MDL 2327
LITIGATION	)	
	)	Joseph R. Goodwin,
	)	U.S. District Judge
CAROL JEAN DIMOCK	)	
	)	Case No.
Plaintiff,	)	2:12-cv-00401
	)	
vs.	)	Videotaped
	)	Deposition of:
ETHICON, INC., et al.,	)	
	)	BOBBY LEWIS SHULL, M.D.
Defendant.	)	

---

March 15, 2016

9:02 a.m.

Location: Beck Redden, LLP  
515 Congress Avenue, Suite 1900  
Austin, Texas 78701

Reporter: Steven Stogel  
Certified LiveNote Reporter, Texas CSR

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES</p> <p>2</p> <p>3 MOTLEY RICE, LLC</p> <p>4 By Margaret Thompson, Esq.</p> <p>5 10 Hale Street, Suite 403</p> <p>6 Charleston, West Virginia 25301</p> <p>7 (304) 344-1100</p> <p>8 mthompsonmd@gmail.com</p> <p>9 For the Plaintiff.</p> <p>10</p> <p>11 BECK REDDEN, LLP</p> <p>12 By W. Curt Webb, Esq.</p> <p>13 1221 McKinney Street, Suite 4500</p> <p>14 Houston, Texas 77010</p> <p>15 (713) 951-6206</p> <p>16 cwebb@beckredden.com</p> <p>17 For Defendants, Johnson &amp; Johnson and Ethicon.</p> <p>18</p> <p>19 ALSO PRESENT: MR. PETER ZIERLEIN, Videographer</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 4</p> <p>1 PROCEEDINGS</p> <p>2 (Exhibit No. 1 marked)</p> <p>3 THE VIDEOGRAPHER: We are now on the</p> <p>4 record. My name is Peter Zierlein. I'm a videographer</p> <p>5 for Golkow Technologies.</p> <p>6 Today's date is March 15th, 2016, and the</p> <p>7 time is 9:02 a.m. This video deposition is being held</p> <p>8 in Austin, Texas, in the matter of Carol Jean Dimock</p> <p>9 versus Ethicon, Inc., for the United States District</p> <p>10 Court, Southern District of West Virginia at Charleston.</p> <p>11 The deponent is Dr. Shull. Will counsel</p> <p>12 please identify yourselves for the record?</p> <p>13 MS. THOMPSON: Margaret Thompson for the</p> <p>14 MDL plaintiffs.</p> <p>15 MR. WEBB: Curt Webb for Ethicon.</p> <p>16 THE VIDEOGRAPHER: The court reporter is</p> <p>17 Steve Stogel and will now swear in the witness.</p> <p>18 BOBBY LEWIS SHULL,</p> <p>19 having been first duly sworn, testified as follows:</p> <p>20 EXAMINATION</p> <p>21 BY MR. WEBB:</p> <p>22 Q. Would you state your full name for the record,</p> <p>23 please?</p> <p>24 A. Bobby Lewis Shull.</p> <p>25 Q. Dr. Shull, my name is Curt Webb. We've met</p>
<p style="text-align: right;">Page 3</p> <p>1 INDEX</p> <p>2 Deposition of: Examination</p> <p>3 BOBBY LEWIS SHULL, M.D.</p> <p>4 By Mr. Webb 4</p> <p>5 By Ms. Thompson 168</p> <p>6 By Mr. Webb 176</p> <p>7</p> <p>8</p> <p>9 EXHIBITS</p> <p>10 No. Page</p> <p>11 1 Notice of Deposition 4</p> <p>12 2 Curriculum Vitae of Bobby Lewis</p> <p>13 Shull, M.D. 5</p> <p>14</p> <p>15 3 Check Stub and Invoices from Dr. Shull 6</p> <p>16</p> <p>17 4 Article Entitled "Tension-free Vaginal</p> <p>18 Tape Bowel Perforation" 37</p> <p>19</p> <p>20 5 Rule 26 Expert Report of Bob Shull, M.D. 100</p> <p>21</p> <p>22 6 Check Stub and Invoices from Dr. Shull 101</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 5</p> <p>1 before. Correct?</p> <p>2 A. Yes, we have.</p> <p>3 Q. And I'm here to take your deposition today in</p> <p>4 regard to, this morning, two products, Prolift and</p> <p>5 Prolift+M. Do you understand that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Okay. I'm going to show you what's been</p> <p>8 marked as Exhibit No. 1, which is the notice of your</p> <p>9 deposition. And once again, you can ignore the Robert</p> <p>10 on there. But other than that, have you seen this</p> <p>11 notice before?</p> <p>12 A. Yes, sir.</p> <p>13 Q. Okay. Dr. Shull, have you brought any</p> <p>14 documents today responsive to the subpoena duces</p> <p>15 tecum that's attached to the notice of deposition?</p> <p>16 A. Yes, sir.</p> <p>17 MS. THOMPSON: And just for the record,</p> <p>18 we filed objections to the duces tecum request.</p> <p>19 A. Yes, sir. I have an updated curriculum vitae.</p> <p>20 The one which, I believe, was appended to the record you</p> <p>21 received did not have a list of all my publications, and</p> <p>22 this one has corrected that omission.</p> <p>23 (Exhibit No. 2 marked)</p> <p>24 Q. (BY MR. WEBB) So this is an updated current</p> <p>25 CV that you've given me which I've marked as Exhibit</p>

2 (Pages 2 to 5)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 6</p> <p>1 No. 2 to your deposition. Is that correct?</p> <p>2 A. Yes, sir.</p> <p>3 Q. All right.</p> <p>4 A. I have the general report for Prolift and</p> <p>5 Prolift+M, and I have a copy of the invoice submitted</p> <p>6 for the work in preparation for Prolift and Prolift+M.</p> <p>7 Q. The Rule 26 expert report that you gave me</p> <p>8 related to Prolift and Prolift+M, has it changed any</p> <p>9 since the one that was filed with the Court?</p> <p>10 A. No, sir, I don't think it has.</p> <p>11 Q. Okay. You've handed me what I'm going to mark</p> <p>12 as Exhibit No. 3 to your deposition.</p> <p>13 (Exhibit No. 3 marked)</p> <p>14 Q. (BY MR. WEBB) And this is a three-page</p> <p>15 document. It looks like the top is a check stub. The</p> <p>16 second is an invoice. The third is some handwritten</p> <p>17 notes related to the billing that you've done for the</p> <p>18 Prolift and Prolift+M general report. Is that correct,</p> <p>19 sir?</p> <p>20 A. Yes, sir.</p> <p>21 Q. Would it be fair to state, according to this</p> <p>22 invoice and the handwritten notes, you had worked a</p> <p>23 total of just a little bit under nine hours at \$650 an</p> <p>24 hour for a total of 5,740?</p> <p>25 A. Yes, sir.</p>	<p style="text-align: right;">Page 8</p> <p>1 with correspondences and with information about Prolift</p> <p>2 in general, and many, if not all of those, are</p> <p>3 referenced in the general report.</p> <p>4 Q. So you have a binder --</p> <p>5 MR. WEBB: And has this information been</p> <p>6 provided to us by the --</p> <p>7 MS. THOMPSON: Yes. And I also have, on</p> <p>8 a thumb drive, documents provided to Dr. Shull.</p> <p>9 MR. WEBB: And does the thumb drive have</p> <p>10 everything that he's referenced here?</p> <p>11 MS. THOMPSON: I believe so.</p> <p>12 MR. WEBB: Okay. Well, we'll run --</p> <p>13 MS. THOMPSON: Certainly with regard to</p> <p>14 Ethicon documents it does. He may have some literature</p> <p>15 of his own. I'm not sure.</p> <p>16 Q. (BY MR. WEBB) So you've got a binder that has</p> <p>17 medical literature?</p> <p>18 A. Yes, sir.</p> <p>19 Q. Would that be correct?</p> <p>20 A. Yes, sir.</p> <p>21 Q. And then you have a box of documents --</p> <p>22 A. Yes, sir.</p> <p>23 Q. -- that were provided to you regarding -- that</p> <p>24 were Ethicon documents?</p> <p>25 A. Yes, sir. And they're here if you would like</p>
<p style="text-align: right;">Page 7</p> <p>1 Q. Okay. This invoice runs through January 23rd,</p> <p>2 2016. Have you done any work since then?</p> <p>3 A. Yes, sir.</p> <p>4 Q. How much?</p> <p>5 A. I don't know the exact time, but I had</p> <p>6 preparation for today's deposition, and that required</p> <p>7 reading my general report again to be familiar with the</p> <p>8 content and references, and I spoke with Dr. Thompson</p> <p>9 yesterday about my preparation for today's presentation.</p> <p>10 Q. All right. Let's go through that. First off,</p> <p>11 you read -- in preparation for today's deposition, you</p> <p>12 read through your general report and just</p> <p>13 re-familiarized yourself. Is that correct?</p> <p>14 A. Yes, sir.</p> <p>15 Q. Did you go through any of the medical</p> <p>16 literature, articles that were referenced in your</p> <p>17 report?</p> <p>18 A. Yes, sir.</p> <p>19 Q. And did you read all the ones that are</p> <p>20 referenced in your report, or did you just read the</p> <p>21 abstracts, or what did you do?</p> <p>22 A. I have a folder that has the information which</p> <p>23 has been referenced with articles, and I have reviewed</p> <p>24 each of those articles again, and I have a box to my</p> <p>25 left which has other documents which were provided to me</p>	<p style="text-align: right;">Page 9</p> <p>1 to see those.</p> <p>2 Q. I'll look at them at the first break.</p> <p>3 A. Okay.</p> <p>4 Q. Did you meet with anyone in preparation for</p> <p>5 this deposition today?</p> <p>6 A. Yes, sir. I met with Dr. Thompson yesterday</p> <p>7 afternoon in my home, and I met with her briefly this</p> <p>8 morning before we arrived for the deposition.</p> <p>9 Q. Tell me how long you spent with Dr. Thompson</p> <p>10 yesterday.</p> <p>11 A. Approximately two hours.</p> <p>12 Q. And what did you go over?</p> <p>13 A. We discussed the format. She wanted to be</p> <p>14 comfortable that I was prepared and I was knowledgeable</p> <p>15 about the subject matter to be covered, so we discussed</p> <p>16 that. We looked at my general report again to confirm</p> <p>17 that it was accurate.</p> <p>18 Q. Anything else in those two hours?</p> <p>19 A. Only that we were going to meet here this</p> <p>20 morning if possible and have breakfast before we came</p> <p>21 for the deposition.</p> <p>22 Q. And did you do that?</p> <p>23 A. Yes, sir.</p> <p>24 Q. What time did you meet this morning?</p> <p>25 A. Probably just a few minutes before 8:00.</p>

3 (Pages 6 to 9)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 10</p> <p>1 Q. All right. Did you discuss anything this</p> <p>2 morning of a substantive matter?</p> <p>3 A. No, sir. Only that we should be here in a</p> <p>4 timely fashion, and I should have the information that I</p> <p>5 have supplied to you. She wanted to confirm that I</p> <p>6 brought that with me.</p> <p>7 Q. Anything else that you've done since the</p> <p>8 invoicing that you've been -- let me just run through</p> <p>9 this. Exhibit No. 3 has -- it looks to be a check stub.</p> <p>10 Have you been paid for the \$5,740 that you had</p> <p>11 invoiced -- well, the invoice just says to Margaret.</p> <p>12 A. It should have said to Margaret Thompson, and</p> <p>13 it comes from -- I believe that it states that it was</p> <p>14 for work done for Prolift. I think it does, but I'm not</p> <p>15 sure that it does. The stub, I'm talking about.</p> <p>16 Q. Well, let me run through them. Exhibit No. 3,</p> <p>17 you've got a check stub that talks about -- a check stub</p> <p>18 for 5,740, and there's an invoice dated February 7th,</p> <p>19 2016. It says, "Prolift and Prolift+M general report."</p> <p>20 The first entry is, "Read draft."</p> <p>21 Explain to me why your first entry would</p> <p>22 be "read draft."</p> <p>23 A. I think it must have been -- oh, to read,</p> <p>24 you're talking about -- I believe the reason it says</p> <p>25 that is because I had drafted a general report for her</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. Tell me, if you will, how many general reports</p> <p>2 on how many different products have you prepared in</p> <p>3 regard to this mesh litigation?</p> <p>4 A. I will tell you that I don't know that for</p> <p>5 certain, but I think there have been two previous</p> <p>6 general reports, if I'm not mistaken, one on a Boston</p> <p>7 Scientific product -- and forgive me if I don't remember</p> <p>8 exactly who made the product, because I may have this</p> <p>9 incorrectly stated. And I believe that I have done</p> <p>10 one -- I've done one on Avaulta. Now, I'm trying to</p> <p>11 remember who the manufacturer for Avaulta is, quite</p> <p>12 honestly.</p> <p>13 Q. So prior to preparing a general report for the</p> <p>14 Prolift and Prolift+M, you had prepared, you think, two</p> <p>15 previous general reports?</p> <p>16 A. I think that's correct. I know I did Avaulta.</p> <p>17 Q. And --</p> <p>18 A. I may have done another.</p> <p>19 Q. Okay. Who else did you -- who did you work</p> <p>20 with in preparing those general reports for the two --</p> <p>21 the two previous general reports that you think that you</p> <p>22 prepared?</p> <p>23 A. Dr. Thompson, primarily.</p> <p>24 Q. We're here today to talk about, in this</p> <p>25 deposition, the -- your opinions with respect to Prolift</p>
<p style="text-align: right;">Page 11</p> <p>1 regarding another product in the past, and I wanted to</p> <p>2 familiarized myself with the format for what was</p> <p>3 required to put into a draft.</p> <p>4 Q. And what product had you prepared a draft</p> <p>5 report for her -- or had prepared a general report for</p> <p>6 her in the past?</p> <p>7 A. You know, I don't have the exact product name,</p> <p>8 but I believe it was one for Boston Scientific. But I</p> <p>9 don't remember the exact product name presently.</p> <p>10 Q. I'm just going to read into the record what</p> <p>11 the invoice says. It says, "January 18, 2016: Read</p> <p>12 draft, 50 minutes. January 21st: Made corrections, 65</p> <p>13 minutes. January 21st: Read reference articles, 190</p> <p>14 minutes. January 22nd: Revise general report to</p> <p>15 reflect supporting articles, 90 minutes. January 22nd:</p> <p>16 Phone call with Margaret and Meghan, 45 minutes.</p> <p>17 January 23rd: Confirm accuracy of cited articles and</p> <p>18 final draft, 90 minutes."</p> <p>19 It's a total of 530 minutes, eight hours</p> <p>20 50 minutes, a total due -- fee, \$650 an hour. Total</p> <p>21 due, \$5,740.</p> <p>22 Does that summarize the work that you</p> <p>23 were doing in regard to preparing a general report for</p> <p>24 Prolift and Prolift+M?</p> <p>25 A. Yes, sir.</p>	<p style="text-align: right;">Page 13</p> <p>1 and Prolift+M. Correct?</p> <p>2 A. Yes, sir.</p> <p>3 Q. You've given opinions in the past with respect</p> <p>4 to Prolift and Prolift+M, haven't you?</p> <p>5 MS. THOMPSON: Object to form.</p> <p>6 A. In a general report? Are you asking me about</p> <p>7 that?</p> <p>8 Q. (BY MR. WEBB) In depositions for these</p> <p>9 products.</p> <p>10 MS. THOMPSON: Same objection.</p> <p>11 A. I gave depositions last week with you for two</p> <p>12 women who had had Prolift products.</p> <p>13 Q. (BY MR. WEBB) Okay. Is there anything about</p> <p>14 the prior testimony, after reviewing the report and</p> <p>15 reviewing the literature, that you want to correct for</p> <p>16 the depositions that we gave regarding Prolift and</p> <p>17 Prolift+M?</p> <p>18 A. No, sir, I can't think of any.</p> <p>19 Q. You also have prepared a general report on</p> <p>20 another product -- Ethicon product, Prosima?</p> <p>21 A. Yes, sir.</p> <p>22 Q. And as we walk through these reports today,</p> <p>23 your opinions are mostly identical for each of these</p> <p>24 products -- Prolift, Prolift+M, and Prosima -- except</p> <p>25 that where you characterized them differently in the</p>

4 (Pages 10 to 13)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 14</p> <p>1 report. For example, there will be paragraphs that are 2 identical as we walk through these reports. Is that 3 correct? 4 A. Some things will be similar and some will vary 5 depending on -- excuse me -- the scientific literature. 6 Some of the internal documents will be the same, and 7 some of the descriptions of my concerns will be the 8 same. 9 Q. Okay. Do you have any kind of a written 10 agreement between Ms. Thompson and yourself about -- or 11 the law firm that she represents or the various law 12 firms about what you will do as far as the work that 13 you'll be doing in this mesh litigation? 14 A. No, sir. Everything has been oral. 15 Q. Are you required to bill anyone else for 16 general work that you do on these products other than 17 Ms. Thompson? 18 A. No, sir. 19 Q. Is the totality of the universe of which 20 you've reviewed the medical literature that you have in 21 front of you and the box of documents -- the Ethicon 22 documents that you have? 23 MS. THOMPSON: Object to form. 24 A. These articles that I have in my own 25 possession that I've used previously for work, for</p>	<p style="text-align: right;">Page 16</p> <p>1 notes on those. 2 Are those your notes? 3 A. Yes, sir. 4 Q. Okay. The second one is "Defining success 5 after surgery for pelvic organ prolapse," and it's in 6 "Obstetrics and Gynecology," Volume 114, No. 3, 7 September of 2009, and once again has handwritten notes 8 and markups on it. 9 Are those your handwritten notes and 10 markups? 11 A. Yes, sir. 12 Q. The final is an article titled "Host response 13 after reconstruction of abdominal wall defects with 14 porcine dermal collagen in a rat model", American 15 Journal of Obstetrics and Gynecologist," 2004. And once 16 again, it has highlighting and markups on the document. 17 Are those your highlighting and markups? 18 A. Yes, sir. 19 Q. And these are articles that generally you had 20 in your possession that you used for your own education 21 or for -- to teach. Is that correct? 22 A. Yes, sir. 23 MR. WEBB: Let's go off the record for a 24 minute. 25 THE VIDEOGRAPHER: Going off the record,</p>
<p style="text-align: right;">Page 15</p> <p>1 journal club, and for teaching and whatnot may not be in 2 this binder. And I have read those in preparation for 3 today, not specifically for one deposition or the other, 4 but I read them in general. So here are three articles 5 which I brought. 6 And I'm not sure -- one of them may 7 already be in the binder. I'm not positive that all 8 three are. 9 Q. (BY MR. WEBB) The material in the binder, did 10 you locate this material yourself, these medical 11 articles, or were they given to you? 12 A. It was a -- this binder was given to me, but 13 of these things that are in the binder, I would say the 14 vast majority I was familiar with already in my role as 15 a teacher and participant in various things. So this 16 was organized and sent to me. 17 Q. Okay. And it was sent to you by plaintiffs' 18 counsel? 19 A. Yes, sir. 20 Q. All right. So you've given me three articles, 21 the top one labeled "Functional and anatomical outcome 22 of anterior and posterior vaginal prolapse repair with 23 Prolene mesh," which was in "BJOG" -- "BJOG: An 24 International Journal of Obstetrics &amp; Gynaecology" dated 25 January of 2005. And it's marked up and has handwritten</p>	<p style="text-align: right;">Page 17</p> <p>1 the time is 9:22. 2 (Recess from 9:22 a.m. to 9:34 a.m.) 3 THE VIDEOGRAPHER: Back on the record, 4 the time is 9:34. 5 Q. (BY MR. WEBB) Dr. Shull, you told me you've 6 got a binder that's in front of you. 7 A. Yes, sir. 8 Q. If you could hold that up just so it will be 9 on the screen. 10 That's a binder that was provided to you 11 that has the articles -- the medical articles that were 12 sent to you by plaintiffs' counsel for you to review in 13 preparation for making your general report for the 14 Prolift and the Prolift+M, correct? 15 MS. THOMPSON: Object to form. 16 A. Yes, I used these articles in the preparation. 17 Q. (BY MR. WEBB) And to your left there's a box 18 that has a number of folders in it that contain 19 documents that were produced by Ethicon. Do you 20 understand that to be what those are? 21 A. Yes, sir. 22 Q. And in that box, there is everything from 23 medical articles to email correspondence to marketing 24 materials, just a variety of different materials. Is 25 that correct?</p>

5 (Pages 14 to 17)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 18</p> <p>1 A. Yes, sir.</p> <p>2 Q. And I would say it's not quite a box full,</p> <p>3 maybe about half a box. Would you say that's about --</p> <p>4 A. Yes.</p> <p>5 Q. -- right?</p> <p>6 A. Yes, sir.</p> <p>7 Q. A banker's box. If I look at your bill -- and</p> <p>8 this is the only bill that you submitted for Prolift and</p> <p>9 Prolift+M in preparation of your general report. Is</p> <p>10 that correct?</p> <p>11 A. Yes, sir.</p> <p>12 Q. And so it would basically entail all the time</p> <p>13 you spent reading all the articles, going through all</p> <p>14 the documents, and preparing your general report and</p> <p>15 working with plaintiffs' counsel in order to finalize</p> <p>16 that general report?</p> <p>17 A. Yes, sir.</p> <p>18 Q. Okay. So the first entry, 50 minutes of</p> <p>19 reading draft, you think that may be a prior general</p> <p>20 report that you did just to get the format down?</p> <p>21 A. I think that's part -- excuse me. I'm losing</p> <p>22 my voice. It's part of it, to get my thoughts organized</p> <p>23 about what is expected in a report by looking at</p> <p>24 something that had been done previously and organizing</p> <p>25 my notes on what I could do on this particular report.</p>	<p style="text-align: right;">Page 20</p> <p>1 some highlighting. Did you go through and make those</p> <p>2 handwritten notes and highlighting as you looked through</p> <p>3 the documents?</p> <p>4 A. Yes, sir.</p> <p>5 Q. There were at least four folders that had</p> <p>6 portions of deposition transcripts. Did you request</p> <p>7 those deposition transcripts, or were they sent to you</p> <p>8 by plaintiffs' counsel?</p> <p>9 A. They were sent to me by plaintiffs' counsel.</p> <p>10 Q. For example, I have one here that's the</p> <p>11 transcript of deposition of Giselle -- is it Bonet,</p> <p>12 B-O-N-E-T?</p> <p>13 A. Yes, sir, that may be the way you pronounce</p> <p>14 it. I don't know that.</p> <p>15 Q. All right. Taken March 5th, 2012, and</p> <p>16 there's -- that's the cover page. There's one other</p> <p>17 page here in this, and it's Page 102. Was that -- for</p> <p>18 the portions of depositions that were given to you, was</p> <p>19 that all that was given was just selected portions of</p> <p>20 those depositions?</p> <p>21 A. Yes, sir.</p> <p>22 Q. Did you ask for the full transcript of the</p> <p>23 deposition in order to put them in context?</p> <p>24 A. No, sir.</p> <p>25 Q. So, for example, in this deposition, for</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. There is an entry for read referenced</p> <p>2 articles, 190 minutes. Does that entail both the binder</p> <p>3 full of medical literature that's in front of you and</p> <p>4 the box of Ethicon documents?</p> <p>5 A. I would have to look at that and see if there</p> <p>6 was anything else mentioned. I actually didn't commit</p> <p>7 this to memory. Yes, sir, I think so.</p> <p>8 Q. Tell me how many medical articles are in that</p> <p>9 binder that are in front of you.</p> <p>10 A. I didn't count them, but I can do that.</p> <p>11 Q. Just a rough estimate, as you look at them.</p> <p>12 A. 20 or 25.</p> <p>13 Q. As I went through the box with the Ethicon</p> <p>14 documents in them, those are not documents you</p> <p>15 requested. Those are documents that were forwarded to</p> <p>16 you that plaintiffs' counsel thought might be helpful in</p> <p>17 preparing your general report. Would that be a fair</p> <p>18 statement?</p> <p>19 A. Yes, sir.</p> <p>20 Q. Did you go through those documents and request</p> <p>21 other documents based upon what you saw in the documents</p> <p>22 that had been sent to you?</p> <p>23 A. I don't recall requesting another document.</p> <p>24 Q. As I went through, for example, I noticed that</p> <p>25 there were some handwritten notes in pen and there was</p>	<p style="text-align: right;">Page 21</p> <p>1 whatever reason, you were given one page, Page 102, out</p> <p>2 of however many pages were in this deposition?</p> <p>3 A. Yes, sir.</p> <p>4 Q. And the reason that you have it marked is</p> <p>5 there's a handwritten note that said, "Kit not studied."</p> <p>6 What does that mean?</p> <p>7 A. May I see it?</p> <p>8 Q. Sure.</p> <p>9 A. And I'll tell you.</p> <p>10 At the top of Page 102 in the deposition,</p> <p>11 Giselle Bonet, the question was, "At the time the</p> <p>12 Prolift, which is trademarked, was launched, the Prolift</p> <p>13 itself had not been studied in clinical studies,</p> <p>14 correct, meaning the actual packaged product with the</p> <p>15 preformed mesh and the instruments had not been studied</p> <p>16 clinically?"</p> <p>17 So the person doing the deposition asked</p> <p>18 that question of Giselle Bonet, and her response was,</p> <p>19 "That's correct. The kit had not been studied."</p> <p>20 So the reason I made this note is to</p> <p>21 remind me that Prolift was marketed without any clinical</p> <p>22 testing.</p> <p>23 Q. Do you know whether or not there was any</p> <p>24 discussion of any other clinical testing anywhere in</p> <p>25 this deposition? Do you have any idea?</p>

6 (Pages 18 to 21)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 22</p> <p>1 A. No, sir.</p> <p>2 Q. So all you know is based upon the one page</p> <p>3 that you were provided out of whatever number of pages</p> <p>4 that was in that transcript?</p> <p>5 A. For that particular folder, that's correct.</p> <p>6 Q. The next folder we're going to look at is a</p> <p>7 folder marked "Kirkemo, Aaron," of a deposition taken</p> <p>8 April 18th, 2012, and it entails one, two -- six pages</p> <p>9 of a deposition, and it's highlighted.</p> <p>10 Did you look at this deposition and make</p> <p>11 the highlighting that's on the deposition portions of</p> <p>12 the deposition that were provided to you?</p> <p>13 A. Yes, sir, I did.</p> <p>14 Q. Okay. Once again, did you ask for these</p> <p>15 portions to be sent to you, or was that just sent to you</p> <p>16 by plaintiffs' counsel?</p> <p>17 A. This was sent to me by plaintiffs' counsel.</p> <p>18 Q. Did you request the entire deposition so you</p> <p>19 could read it all and put it in context?</p> <p>20 A. No, sir, I did not.</p> <p>21 Q. Page 1 is the cover page. The next labeled</p> <p>22 page is 135, 136, 137, 138, and then it skips to 150.</p> <p>23 Do you have any idea how long this</p> <p>24 deposition was?</p> <p>25 A. No, sir.</p>	<p style="text-align: right;">Page 24</p> <p>1 A. No, sir.</p> <p>2 Q. Did you ask for the entire deposition so you</p> <p>3 could put it into context and see if there was anything</p> <p>4 else that was significant?</p> <p>5 A. No, sir.</p> <p>6 Q. Were you given any complete transcript of any</p> <p>7 deposition that's been taken in any of the mesh</p> <p>8 litigation by plaintiffs' counsel in preparation for</p> <p>9 doing your general report for Prolift and Prolift+M?</p> <p>10 A. No, sir.</p> <p>11 Q. Have you ever made any request for any Ethicon</p> <p>12 documents that have not been provided to you?</p> <p>13 A. No, sir.</p> <p>14 Q. One of the things that we asked in the</p> <p>15 subpoena duces tecum was a list of the cases. Have you</p> <p>16 provided a list of all the cases that you have --</p> <p>17 A. Yes, sir. I thought that was appended. If it</p> <p>18 isn't appended to that --</p> <p>19 Q. Appended to your general report?</p> <p>20 A. Yes, sir. If it isn't appended to that --</p> <p>21 this is for later when you ask me about Prosima. I</p> <p>22 actually thought both of them had something, but maybe</p> <p>23 that one doesn't have it. It wouldn't be behind my</p> <p>24 curriculum vitae. It would be behind the general</p> <p>25 report. But this would be the one that would be similar</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. The next deposition, the name on it is Hinoul,</p> <p>2 H-I-N-O-U-L, P-I-E-T, dated April 6, 2012.</p> <p>3 Once again, was this portion of a</p> <p>4 deposition transcript provided to you by plaintiffs'</p> <p>5 counsel?</p> <p>6 A. Yes, sir.</p> <p>7 Q. Did you ask for the entire deposition so you</p> <p>8 could put it into context?</p> <p>9 A. No, sir.</p> <p>10 Q. It has two pages, the first page is</p> <p>11 Volume 2 -- or it's a cover page for Volume 2, which is</p> <p>12 marked Page 351, and the one page actually has four</p> <p>13 pages from the deposition on this one-page transcript --</p> <p>14 from the transcript. Those are labeled Page 504, 505,</p> <p>15 506, and 507.</p> <p>16 Did you ask for the entire deposition in</p> <p>17 order to put this in context?</p> <p>18 A. No, sir.</p> <p>19 Q. And the final one that I found in the box that</p> <p>20 you had that had been provided by plaintiffs' counsel is</p> <p>21 a deposition taken of Scott Hamilton Jones dated</p> <p>22 January 25th, 2012. This is Volume 3, Page 654, and</p> <p>23 there are three actual pages of deposition testimony</p> <p>24 from Page 727, 728, and 729.</p> <p>25 Did you request these pages specifically?</p>	<p style="text-align: right;">Page 25</p> <p>1 for both of them. Yes, sir.</p> <p>2 Q. Okay. And the request -- what I have for you,</p> <p>3 other than the depositions that were taken last week in</p> <p>4 case-specific matters, does this list that's appended to</p> <p>5 your expert report, your general report, is it a</p> <p>6 complete list other than the ones we had last week?</p> <p>7 A. The only thing I see differently, now that</p> <p>8 you've asked me specifically about it, is last week when</p> <p>9 you deposed me, I told you there was one person's name</p> <p>10 on the list, Mrs. Rabiola, R-A-B-I-O-L-A, and I was</p> <p>11 deposed because I was a treating physician for her. I</p> <p>12 wasn't deposed --</p> <p>13 Q. As an expert?</p> <p>14 A. No, sir.</p> <p>15 Q. Testifying expert?</p> <p>16 A. No, sir. Josephine Rabiola. And I just see</p> <p>17 that this isn't on this, and I'm not certain why. But</p> <p>18 you and I talked about that last week, that I was a</p> <p>19 treating physician for her.</p> <p>20 Q. When were you first contacted by anyone in</p> <p>21 regard to giving expert testimony in regard to Prolift</p> <p>22 and Prolift+M products?</p> <p>23 A. I don't have the exact date, but it would have</p> <p>24 been sometime in the last quarter of 2015. I believe</p> <p>25 that would be correct. I was asked if I would do it,</p>

7 (Pages 22 to 25)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 26</p> <p>1 and I was given a potential window of time that the work  2 would need to be performed, but it wasn't immediate at  3 the time that I discussed it with Dr. Thompson.  4 Q. Was she the individual that contacted you?  5 A. Yes, sir.  6 Q. And when you say Dr. Thompson, are you  7 referring also to the lawyer that is presenting you for  8 deposition today?  9 A. Yes, sir, Dr. Margaret Thompson, who is also  10 an attorney.  11 Q. What did she ask you to do?  12 A. She asked me to work with her on preparing a  13 general report about the products Prolift and Prosima.  14 Q. Any other work that she asked you to do?  15 A. Not specifically at that time, no, sir.  16 Q. Okay. Give me a ballpark, if you will, on how  17 much you've earned in this litigation since you were  18 first contacted by Dr. Thompson up to the current -- and  19 I understand you haven't invoiced for everything. You  20 invoiced for individual cases. But just generally give  21 me an idea if you can, Doctor.  22 A. Well, I think -- yes, sir.  23 MS. THOMPSON: Object to form.  24 A. Yes, sir. I think last week on the  25 case-specific report, I submitted the invoices to you.</p>	<p style="text-align: right;">Page 28</p> <p>1 depositions and the preparation and deposition time  2 today?  3 A. Yes, sir, that's correct.  4 Q. When you have a patient that comes in that has  5 a mesh product already implanted in that patient, do you  6 inform them that you are a plaintiff -- that you're an  7 expert for the plaintiffs in this mesh litigation?  8 A. I don't think that's ever come up, no, sir.  9 Q. When you draft these reports, were you given a  10 template to go by in order to lay out the format that  11 you should prepare your expert report in?  12 MS. THOMPSON: Objection to questions  13 about the drafting of the reports.  14 A. Well, I have to --  15 MS. THOMPSON: And anything that goes too  16 much beyond this, I'm going to instruct him not to  17 answer.  18 A. I have to have some idea about what is  19 reasonable from a legal standpoint, because that's not  20 in my normal area of knowledge, so I have to have some  21 guidance about how to construct a report, if that's what  22 you're asking me. I've spoken with Dr. Thompson about  23 what would be a reasonable format to present that is a  24 fair assessment of my own observations and is something  25 that would be expected in a legal proceeding.</p>
<p style="text-align: right;">Page 27</p> <p>1 Honestly, I don't know the exact amount, but I would say  2 it was approximately -- it may have been 26 or \$28,000.  3 I don't know that. Maybe that's high. I don't remember  4 that exactly, to be quite honest with you. There were  5 three cases -- that's not correct. It probably was 15  6 or \$20,000, actually.  7 What I told you was incorrect because  8 there were three case specifics. And I think each was  9 five or so thousand dollars, so it was probably 15 or so  10 thousand dollars.  11 Q. (BY MR. WEBB) So would you say -- if we tried  12 to approximate not only the case-specific work that  13 you've done, but also the work on Prolift and Prosima,  14 that -- generally we could say it's under \$50,000,  15 roughly?  16 A. Yes, sir.  17 Q. Okay.  18 A. At this point, it's probably closer to 25 or  19 \$30,000.  20 Q. Okay. So 25 or 30 would be a better estimate  21 in your mind --  22 A. That would be the two general reports and the  23 three case-specific reports.  24 Q. And does not include the time that you spent  25 that you didn't invoice for for last week for the</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. (BY MR. WEBB) Prior to getting involved in  2 this mesh litigation, had you ever prepared an expert  3 report for any expert testimony that you had given in  4 any litigation?  5 A. No, sir.  6 Q. As we go through your expert report, which we  7 will do, there are medical literature that are  8 summarized -- would that be a fair statement -- in your  9 expert report?  10 A. Yes, sir.  11 Q. Do all of these articles that are listed in  12 your expert report for Prolift and Prolift+M, did they  13 come out of that binder that was provided to you by  14 plaintiffs' counsel?  15 MS. THOMPSON: Object to form.  16 A. I believe that's correct.  17 Q. (BY MR. WEBB) Did --  18 A. I believe that's accurate.  19 Q. Okay. Did you put in any article or any  20 abstract that you found on your own that was not  21 provided to you by plaintiffs' counsel?  22 MS. THOMPSON: Object to form.  23 A. That is referenced in the general report? Is  24 that what you're asking?  25 Q. (BY MR. WEBB) Correct.</p>

8 (Pages 26 to 29)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 30</p> <p>1 A. To the best of my knowledge, I did not.</p> <p>2 Q. Did you go do a review of the medical</p> <p>3 literature to see if there were articles that showed</p> <p>4 different results from the articles that you -- were</p> <p>5 given to you by plaintiffs' counsel?</p> <p>6 MS. THOMPSON: Object to form.</p> <p>7 A. Well, if you're asking me is this the only</p> <p>8 literature I'm familiar with, the answer is, no, it</p> <p>9 isn't.</p> <p>10 And are there articles that I have read</p> <p>11 that aren't in this? And there are.</p> <p>12 My -- part of my responsibility in</p> <p>13 reviewing the available articles is to look at the</p> <p>14 scientific approach that was taken and then review the</p> <p>15 conclusions because, in many articles, there are --</p> <p>16 there would be more than one way to interpret the</p> <p>17 outcome.</p> <p>18 So my job is to look at that and try to</p> <p>19 determine is there some other message in these articles</p> <p>20 that might be helpful in reaching a decision about</p> <p>21 the -- in this case, the products which are being</p> <p>22 reviewed, Prolift and Prolift+M.</p> <p>23 MR. WEBB: Object to responsiveness of</p> <p>24 the answer.</p> <p>25 Q. (BY MR. WEBB) The question I asked: Did you</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. (BY MR. WEBB) Listen to the question, then.</p> <p>2 My question is: Did you go and do some independent</p> <p>3 research and pull an article from a medical journal and</p> <p>4 use it in your general report other than the articles</p> <p>5 that were prepared and sent to you by plaintiffs'</p> <p>6 counsel?</p> <p>7 MS. THOMPSON: Object to form, now asked</p> <p>8 and answered.</p> <p>9 A. Well, I will answer that. These came partly</p> <p>10 from my request and partly what was given, so I asked</p> <p>11 for part of these. So the answer is I didn't have</p> <p>12 anything that isn't in here, but these weren't all</p> <p>13 spontaneously given to me. I requested some of these.</p> <p>14 And I gave you copies of a couple of things otherwise</p> <p>15 that aren't in here that specifically I did look for. I</p> <p>16 mean, at the beginning, I gave you those, for example.</p> <p>17 Q. (BY MR. WEBB) The three articles that you</p> <p>18 gave me before, are any of those three articles</p> <p>19 summarized in your general report on Prolift or</p> <p>20 Prolift+M?</p> <p>21 A. No, sir. The background knowledge of it is,</p> <p>22 though. The concepts are. For example, what is a</p> <p>23 successful outcome of surgery, which is one of the ones</p> <p>24 I think that's on the top -- or is in that stack of</p> <p>25 three, how do you assess the outcomes of surgery.</p>
<p style="text-align: right;">Page 31</p> <p>1 do any independent research and go find any other</p> <p>2 medical articles other than the ones that were provided</p> <p>3 to you by plaintiffs' counsel?</p> <p>4 A. Yes.</p> <p>5 MS. THOMPSON: Object to form.</p> <p>6 A. Yes, sir. I subscribe to multiple journals</p> <p>7 and review them on a regular basis, and not everything I</p> <p>8 reviewed is in here.</p> <p>9 Q. (BY MR. WEBB) No. The question is: Did you</p> <p>10 go do -- when you were preparing your general report for</p> <p>11 Prolift and Prolift+M, did you go find any article and</p> <p>12 use that article and abstract it or summarize it in your</p> <p>13 general report other than the ones that were provided to</p> <p>14 you in that binder?</p> <p>15 MS. THOMPSON: Object to form.</p> <p>16 A. I don't think I found any different than what</p> <p>17 I have. I think everything I have is here.</p> <p>18 Q. (BY MR. WEBB) Dr. Shull, the question is:</p> <p>19 Did you go do any independent research and pull any</p> <p>20 other article other than the ones that had been provided</p> <p>21 to you for use in preparing your general report?</p> <p>22 MS. THOMPSON: Object to form.</p> <p>23 A. Well, I think what was provided is what I</p> <p>24 asked for. So part of what I asked for would be in</p> <p>25 here. I don't know how to answer that any more clearly.</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. And that's fair for your general background</p> <p>2 knowledge that you used to develop an expert opinion,</p> <p>3 but you actually went through and abstracted or</p> <p>4 summarized articles in --</p> <p>5 A. Yes, sir.</p> <p>6 Q. -- your general report. Are any of these</p> <p>7 three articles abstracted or summarized in your general</p> <p>8 report?</p> <p>9 A. No, sir.</p> <p>10 Q. You state in your expert report on Prolift and</p> <p>11 Prolift+M that you have seen -- you have personally</p> <p>12 examined, diagnosed, and treated approximately 100</p> <p>13 patients with mesh complications and removed some mesh</p> <p>14 from at least 70 women. Is that correct?</p> <p>15 A. Yes, sir.</p> <p>16 Q. Have you prepared any type of formal report or</p> <p>17 summary of the complications you have seen? Have you</p> <p>18 submitted it to any peer-reviewed medical journal for</p> <p>19 publication?</p> <p>20 MS. THOMPSON: Object to form.</p> <p>21 A. The one that's --</p> <p>22 MR. WEBB: Wait a minute. What's the</p> <p>23 problem with that?</p> <p>24 MS. THOMPSON: It was compound.</p> <p>25 MR. WEBB: Read the question.</p>

9 (Pages 30 to 33)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 34</p> <p>1 MS. THOMPSON: "Have you prepared any 2 type of formal report or summary of the complications 3 that you've seen? Have you submitted it to any 4 peer-reviewed medical journal for publication?" 5 MR. WEBB: You think that's compound? 6 MS. THOMPSON: Well, I think there are 7 three questions in there. 8 MR. WEBB: All right. Let's break it 9 down. 10 Q. (BY MR. WEBB) Have you prepared any kind of 11 formal report based upon the summary -- based upon your 12 examination and treatment of these 100 patients? 13 A. I have one case report. I don't have a 14 summary of all of them. 15 Q. Okay. Have you prepared any kind of article 16 and submitted it to any medical journal summarizing the 17 treatment of these patients that you've seen? 18 A. No, sir. Only the one that was a case report. 19 Q. And have you submitted any complaints or made 20 any complaints to the FDA about any of the products that 21 you saw in these patients who you have treated? 22 A. We have a fellowship program, so we educate 23 other people who are going to have skills in the subset 24 of female pelvic medicine, reconstructive surgery. So 25 our fellows have reported a few of these, but certainly</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. And what you're telling me is this is a range 2 of all mesh products over a period of -- when is the 3 last time you saw someone that had a problem? 4 A. You know, probably in the end of calendar year 5 2015. 6 Q. So roughly, you would say, a ten-year period? 7 A. Yes, sir, more or less. 8 Q. And in that ten-year period, you've seen 9 approximately 100 women who you say had a variety of 10 different products across the spectrum of the surgeries 11 that use gynecological mesh for repair of various 12 problems? 13 A. Yes, sir. 14 Q. Okay. How many of that 100 were either 15 Prolift or Prolift+M? 16 A. You know, I don't know the exact answer to 17 that because some patients don't know for certain which 18 product was used, and we don't have the operative note. 19 In some of them I did know that for a fact. 20 So some of them, including the case 21 report we gave, which is in my bibliography, is 22 specifically Prolift. Yes, sir. And this would be the 23 tension-free vaginal tape, the article you've referenced 24 here. 25 Q. Is that the case report you're talking about?</p>
<p style="text-align: right;">Page 35</p> <p>1 not all of them. But I personally have not done that. 2 They've done it at my request. 3 Q. You've reported complications that you've seen 4 in patients to the FDA not personally, but you've had 5 some of your fellows make those reports? 6 A. Yes, sir. 7 Q. Okay. Have you -- were those reports made 8 prior to you signing on as an expert for the plaintiffs 9 in this mesh litigation or after? 10 A. It was before. This was early on -- excuse 11 me. This was early in our experience. 12 Q. When did you first start seeing patients that 13 had complications with mesh? You said you've seen about 14 100? 15 A. Yes, sir. 16 Q. When would have been the first one? 17 A. You know, I don't know the exact date, but I'm 18 going to say in the neighborhood of 2004 or '5. 19 Q. Okay. 20 A. Because when I say I've seen complications, it 21 has meant suburethral slings, it has meant mesh 22 implanted for prolapse, it has meant abdominal 23 sacrocolpopexy. So it's all of those things, including 24 mesh for transvaginal reconstructive surgery. So 25 somewhere in the range of 2004, 2005.</p>	<p style="text-align: right;">Page 37</p> <p>1 A. Yes, sir. There is -- no, sir. This is not 2 the one I was referring to. This is one using 3 tension-free vaginal tape for urinary incontinence. 4 The article I was referencing is one on 5 erosion of a Prolift into the rectum, and one of our 6 fellows reported on one other patient -- Dr. Chris Chung 7 reported on a patient, and I'm not sure if that's in my 8 bibliography or not, because some of the things the 9 fellows do I would have participated in the publication, 10 and some of them I wouldn't have. 11 (Exhibit No. 4 marked) 12 Q. (BY MR. WEBB) I've marked as Exhibit No. 4 a 13 case report titled "Tension-free vaginal tape bowel 14 perforation." 15 A. Yes, sir. 16 Q. And this is in the International 17 Urogynecological Journal of 2010. Is that right? 18 A. Yes, sir. 19 Q. And you were one of the authors on this case 20 report? 21 A. Yes, sir, that's correct. 22 Q. This case report has nothing to do with either 23 Prolift or Prolift+M, does it? 24 MS. THOMPSON: Object to form. 25 A. It does not.</p>

10 (Pages 34 to 37)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 38</p> <p>1 Q. (BY MR. WEBB) And, in fact, in this case  2 report what you're actually reporting on is a problem  3 where there was a perforation of the bowel due to the  4 technique of the physician?  5 MS. THOMPSON: Object to form.  6 A. This article on tension-free vaginal tape  7 bowel perforation refers to a technical issue with  8 placement of a retropubic tension-free vaginal tape, and  9 the bowel was perforated by the trocar.  10 Q. (BY MR. WEBB) And actually the tape was  11 actually placed through the bowel. Is that correct?  12 A. Yes, sir, that's correct.  13 Q. You told me that you think that some of the  14 100 women that you saw had Prolift or Prolift+M. Can  15 you give me an approximation of how many of those  16 patients had Prolift or Prolift+M?  17 A. I can --  18 MS. THOMPSON: Objection; asked and  19 answered.  20 A. Yes, sir, I could do that, but I can't  21 validate it.  22 I know there have been -- I know for a  23 fact there have been at least two patients -- because I  24 remember them -- who knew the product, and it was  25 Prolift. There may be others, but I didn't go back in</p>	<p style="text-align: right;">Page 40</p> <p>1 A. There are four of us -- excuse me -- in our  2 department who see women with disorders of the pelvic  3 floor. Two of us, I feel certain, have not used Prolift  4 products. I know that I haven't, and I believe that  5 Dr. Paul Yandell has not.  6 We have two other colleagues who received  7 as part of their education and/or practiced elsewhere  8 before they came to work for us, and these two  9 individuals, I could not tell you whether or not they've  10 ever used Prolift or Prolift+M elsewhere.  11 To the best of my knowledge, they have  12 not used it while working in our department.  13 Q. When you do training, do you -- have you ever  14 done any training with Prolift or Prolift+M products?  15 A. You mean in being taught myself or in teaching  16 someone else?  17 Q. Both.  18 A. No, sir.  19 Q. Have you ever involve -- been involved in any  20 clinical study involving pelvic mesh products in  21 general?  22 MS. THOMPSON: Object to form.  23 A. No clinic study. Our research group studied  24 Pelvicol in an animal model, but we haven't had a  25 clinical study of any product.</p>
<p style="text-align: right;">Page 39</p> <p>1 preparation for today to look at that and try to  2 abstract that information from the records.  3 Q. (BY MR. WEBB) Did you do a specific  4 literature search -- medical literature search for  5 either complications related to Prolift or complications  6 related to Prolift+M products?  7 A. In preparation for this general report, you're  8 asking?  9 Q. For any reason at all, but especially in  10 representation for this general report?  11 A. Well, not specifically in preparation for this  12 report. I've looked at that previously, but, no, I  13 didn't for this.  14 Q. When did you look at it?  15 A. Oh, I can't give you a specific date. Again,  16 in the education of other people, it's a part of what we  17 do is to review literature and discuss it. So I don't  18 have the exact date for that.  19 Q. Have you ever personally used either Prolift  20 or Prolift+M in any type of surgery?  21 A. No, sir.  22 Q. Have any of your people that work in your  23 practice, the other physicians that are in your  24 practice, do they either use Prolift or Prolift+M for  25 surgery?</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. (BY MR. WEBB) If we go through your  2 bibliography, have you written articles on urinary  3 incontinence?  4 A. Yes, sir.  5 Q. And pelvic organ prolapse?  6 A. Yes, sir.  7 Q. Any articles on surgical mesh?  8 A. Only these case reports and an editorial. But  9 I didn't do a scientific report on mesh, but there's an  10 editorial with Dr. Linda Brubaker. I believe it was  11 published in either 2011 or 2012.  12 Q. Have you ever written any kind of scientific  13 report or medical article in the peer-reviewed  14 literature related -- about how to remove pelvic mesh  15 products?  16 A. No, sir.  17 Q. When you did any explantation of any mesh  18 product, have you done -- has all the mesh product that  19 you have had explanted been sent to pathologists for  20 review?  21 A. Yes, sir, to the best of my knowledge, it has  22 been. I mean, it's entirely possible that I removed --  23 let's use, for an example, a piece of a midurethral  24 sling that was visible and I could measure it and  25 comment on it, and there was no gross evidence of</p>

11 (Pages 38 to 41)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 42</p> <p>1 anything other than it was exposed, I may not have sent 2 that to pathology, but I wouldn't know how to go back 3 and learn exactly how often that would have happened. 4 Q. Has there been any evidence in any of the 5 pathology reports that you received that indicated any 6 type of degradation or breakdown of any of the surgical 7 mesh? 8 A. In our particular organization, what we would 9 normally receive as a report is a confirmation that a 10 sample had been submitted. Usually the dimensions would 11 be included in number of centimeters in length and 12 width. Sometimes it's just a gross description that the 13 pathologist confirmed that we submitted something that 14 was a particular size and it had other tissue attached 15 to it. 16 Sometimes it would be a microscopic 17 evaluation, but not always. And the microscopic 18 examinations, I think it would be exceptional that I 19 would have received a report that commented on 20 degradation. 21 Q. Can you remember, as you sit here today, ever 22 receiving a report that commented on degradation? 23 A. I'm not sure that I have. If I had to guess, 24 I would say I probably have not. 25 Q. Do you believe it's below the standard of care</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. (BY MR. WEBB) From your review of the Ethicon 2 literature, what stages of pelvic organ prolapse would 3 Prolift and Prolift+M be used to treat? 4 MS. THOMPSON: Object to form. 5 A. When I -- 6 MR. WEBB: On what basis? 7 MS. THOMPSON: "Ethicon literature." 8 Does that mean Ethicon sponsored? Ethicon published? 9 MR. WEBB: Forget it. 10 Q. (BY MR. WEBB) Go ahead. 11 MS. THOMPSON: I just don't understand -- 12 MR. WEBB: Forget it. 13 MS. THOMPSON: -- "Ethicon literature," 14 what that means. 15 Q. (BY MR. WEBB) Do you understand what "Ethicon 16 literature" means? 17 A. If you mean the information for users, for 18 example, I think I can comment on that. 19 Q. Can you also comment on all the Ethicon 20 documents that you were provided in the emails -- the 21 general -- any question about any Ethicon document or 22 literature that you reviewed, can you tell me, based 23 upon that, what stages of POP would use either Prolift 24 or Prolift+M to treat? 25 A. I would say, in general, what I think I can</p>
<p style="text-align: right;">Page 43</p> <p>1 to use transvaginal mesh implants? 2 MS. THOMPSON: Object to form. 3 A. Surgery is a job, and it is like, I think, 4 practically every job else, there are more -- there is 5 more than one way to accomplish what you are going to 6 do. I personally have chosen not to use mesh products 7 for transvaginal repair for prolapse. Other people do, 8 and I'm not suggesting that's below the standard of 9 care, but it's an option. It's an option that I haven't 10 chosen. 11 Q. (BY MR. WEBB) You've done some rabbit 12 studies? 13 A. Yes, sir, the people in my research group. I 14 don't think my name was on the article, but they 15 implanted Pelvicol in the vaginal canal of rabbits and 16 reported on the response to the Pelvicol. 17 Q. Does it have anything to do -- that bears 18 directly on this litigation? 19 A. No -- 20 MS. THOMPSON: Object to form. 21 A. There was no comparison with Prolene, for 22 example, so we did not use a Prolene product. 23 THE REPORTER: A Prolene what? 24 THE WITNESS: A Prolene product. 25 THE REPORTER: Thank you.</p>	<p style="text-align: right;">Page 45</p> <p>1 glean from that is if the patient were symptomatic, and 2 that then doesn't lend itself to a quantification of any 3 kind, but if a woman has symptomatic -- excuse me -- 4 pelvic organ prolapse, they may be a candidate. 5 But in terms of assigning that to a 6 particular stage or grade or degree of prolapse, I don't 7 believe that I have seen that in any of the literature. 8 Q. Based upon prior depositions and your opinions 9 that you provided, you prefer the use of native tissue 10 in your surgeries for prolapse. Is that correct? 11 A. Yes, sir. 12 Q. You belong to a number of different 13 professional societies that specialize in this area. 14 Would that be a fair statement? 15 A. Yes, sir. 16 Q. And as any specialist, there's a limited 17 horizon of people that both have the experience and 18 belong to those professional societies. Would you agree 19 with that? 20 A. Yes, sir. 21 Q. Is there any consensus among the specialists 22 in these gynecological societies that you belong to, or 23 urogynecological societies that you belong to, about 24 whether there are benefits that outweigh the risks or 25 risks that outweigh the benefits of the use of</p>

12 (Pages 42 to 45)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 46</p> <p>1 transvaginal mesh?</p> <p>2 MS. THOMPSON: Object to form.</p> <p>3 A. When I -- excuse me -- referred to the article</p> <p>4 that I handed you by Dr. Barber and his associates about</p> <p>5 assessing the outcomes of surgery, in -- I want to apply</p> <p>6 it to these groups.</p> <p>7 So the groups that I belong to who are</p> <p>8 interested in caring for women with pelvic organ</p> <p>9 prolapse have been looking primarily for an improvement</p> <p>10 in the anatomical outcomes of surgery for poor support.</p> <p>11 And as I understand it, I believe there</p> <p>12 is a consensus that surgery of any kind doesn't work for</p> <p>13 all people all the time. And if we could do something</p> <p>14 to reduce the failure with anatomical outcomes, that</p> <p>15 would be desirable.</p> <p>16 And one of the thoughts about using any</p> <p>17 product, whether it's biological or synthetic or</p> <p>18 autologous or xenograft is to try to improve on those</p> <p>19 anatomical outcomes.</p> <p>20 So in that broad context, I think people</p> <p>21 agree that that's a laudable goal. And then the</p> <p>22 question where their ideas diverge is how do you go</p> <p>23 about learning about that.</p> <p>24 So once -- I think under ideal</p> <p>25 circumstances, most people would say, "We would like to</p>	<p style="text-align: right;">Page 48</p> <p>1 patient.</p> <p>2 Q. (BY MR. WEBB) In your report on Prolift</p> <p>3 products, you cite a recent report by Stanford stating</p> <p>4 that most studies shows an anatomic success rate of</p> <p>5 about 92 percent for mesh. Do you remember that --</p> <p>6 A. Yes, sir.</p> <p>7 Q. -- statement?</p> <p>8 A. Yes, sir.</p> <p>9 Q. Do you agree with that statistic you cited?</p> <p>10 A. Well, I have the article here referenced in</p> <p>11 front of me, and I believe in his assessment of the</p> <p>12 literature that there are varying reports on the</p> <p>13 anatomical outcome.</p> <p>14 So when anatomy is the primary endpoint</p> <p>15 of the outcome, that's a fairly well defined issue.</p> <p>16 The -- I'll just say in general, the area of confusion</p> <p>17 about anatomy is not that it's evaluated, but we don't</p> <p>18 know what is a reasonable anatomical outcome to expect</p> <p>19 in a woman of various ages.</p> <p>20 For example, women who are 18 or 20 who</p> <p>21 have never had a baby or have never been traumatized in</p> <p>22 any way may have one set of physical exams which we</p> <p>23 could describe, and under ideal circumstances, maybe we</p> <p>24 could recreate that with surgery, but that isn't what</p> <p>25 most people have. So that may not be a realistic</p>
<p style="text-align: right;">Page 47</p> <p>1 have as much scientific information as we can that</p> <p>2 something is not only effective but that we know about</p> <p>3 the other parameters, including possible injuries or</p> <p>4 side effects associated with it."</p> <p>5 And so that's what people would like to</p> <p>6 know. I think everyone would like to know those things.</p> <p>7 In terms of which method of approach for</p> <p>8 surgery, as I alluded to earlier, surgery is a job, and</p> <p>9 not everyone is going to choose to do the same thing.</p> <p>10 For example, some people are very technically skilled</p> <p>11 with abdominal sacrocolpopexy, and that may be their</p> <p>12 operation of choice. Other people may be very skilled</p> <p>13 vaginally, and that may be their operation of choice.</p> <p>14 And there's another group of people who</p> <p>15 may be skilled in either one of those who feels that</p> <p>16 maybe using a mesh -- synthetic mesh complement to their</p> <p>17 surgery would be beneficial. So we certainly fall into</p> <p>18 those different groups. And once we get to there, I</p> <p>19 don't think there's a consensus.</p> <p>20 Q. (BY MR. WEBB) Okay. You will agree that</p> <p>21 there are good doctors on both sides of this debate --</p> <p>22 or all sides of this debate?</p> <p>23 MS. THOMPSON: Object to form.</p> <p>24 A. I believe that there are honest people raising</p> <p>25 these questions and wanting to do what's best for the</p>	<p style="text-align: right;">Page 49</p> <p>1 anatomic outcome.</p> <p>2 What is -- I believe most doctors have</p> <p>3 now come to a consensus about is a good anatomical</p> <p>4 outcome is one in which no compartment of the vaginal</p> <p>5 canal, either anterior or posterior, prolapses outside</p> <p>6 the hymen, the opening to the vaginal canal. When we</p> <p>7 use that as an endpoint, all of the surgical outcomes</p> <p>8 appear to be better.</p> <p>9 When we're more rigid -- whether it's</p> <p>10 mesh or not mesh, when we're more rigid, the</p> <p>11 unsatisfactory outcomes from the standpoint of just</p> <p>12 looking at the anatomy are greater.</p> <p>13 What Dr. Barber's article points out is</p> <p>14 it isn't only anatomy. It's also the patient's</p> <p>15 perception of what's going on, and it's did they require</p> <p>16 more intervention. So he has those three parameters.</p> <p>17 And when you look at all three of those</p> <p>18 parameters, each of these authors, I believe, would</p> <p>19 report that the outcomes of surgery are better than when</p> <p>20 you have rigid anatomic outcomes. That's been an</p> <p>21 evolution in our reporting system -- actually, a good</p> <p>22 evolution.</p> <p>23 Q. Are you personally critical of all uses of a</p> <p>24 polypropylene mesh for pelvic reconstruction?</p> <p>25 A. I haven't chosen to use it. If you're asking</p>

13 (Pages 46 to 49)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 50</p> <p>1 me am I critical of using it for everybody under every  2 circumstance, that's an individual decision for each  3 doctor and patient to make.  4 In my own personal experience, I am not  5 convinced that given my ability to accomplish what I  6 want to accomplish technically, that the benefits of  7 adding a polypropylene mesh is greater than the side  8 effect. So in my own hands, I have chosen not to do  9 that.  10 Q. You have associates in your own practice,  11 though, who perform sacrocolpopexy using polypropylene  12 mesh. Right?  13 A. Yes, sir. Through the abdomen, they do. And  14 we use it in the suburethral slings. So each of us have  15 used these midurethral slings, which are made of  16 polypropylene.  17 The area where I think we are less likely  18 and perhaps haven't used mesh in our institution is for  19 transvaginal repair of prolapse.  20 Q. And the product that your associates use and  21 the product that you use for the suburethral slings is  22 usually an Ethicon product?  23 A. Yes, sir. And some of that depends on what  24 the organizational purchase is, because all  25 organizations now are trying to bring standardization to</p>	<p style="text-align: right;">Page 52</p> <p>1 referring to here?  2 A. I found no evidence that the product  3 consisting of the mesh with the attached trocars had  4 been used in women in a systematic fashion with  5 information collected about the morbidity, the anatomic  6 outcomes, and the potential for risk associated with  7 this specific kit of the Gynecare mesh, Gynemesh, and  8 the trocars, which is how Prolift was marketed.  9 Q. The individual mesh had been on the market for  10 other uses for a number of years. Would you agree with  11 that?  12 A. Yes, sir.  13 Q. The trocars, were there anything unique or  14 special or brand new about those?  15 MS. THOMPSON: Object to form.  16 A. The trocars in and of themselves, to the best  17 of my knowledge, are not unique. The use of the trocars  18 to penetrate spaces in the pelvis and then to deploy the  19 mesh arms into those spaces, in fact, was a new concept.  20 Q. (BY MR. WEBB) So it's not the complaint about  21 the kit being unique or special. It's the technique  22 that was used to place the mesh in the woman's body. Is  23 that correct?  24 MS. THOMPSON: Object to form.  25 A. As I understand it, from my review of the</p>
<p style="text-align: right;">Page 51</p> <p>1 the purchases. So we have used some other products, but  2 I would say the preponderance of what we use has been  3 from Gynecare, J&amp;J. I'm sorry. My voice is --  4 MR. WEBB: Let's take a little break,  5 give you a chance to get some water.  6 MS. THOMPSON: I was just --  7 THE VIDEOGRAPHER: Going off the  8 record --  9 THE WITNESS: Thank you.  10 THE VIDEOGRAPHER: Going off the record,  11 the time is 10:26.  12 (Recess from 10:26 a.m. to 10:43 a.m.)  13 THE VIDEOGRAPHER: Back on the record.  14 This marks the beginning of Disc No. 2. The time is  15 10:43.  16 Q. (BY MR. WEBB) I'm going to walk through some  17 of the opinions that you expressed related to the  18 Prolift and Prolift+M devices --  19 A. Yes, sir.  20 Q. -- for pelvic organ prolapse.  21 Your first opinion is, "At the time of  22 introduction, there was insufficient scientific evidence  23 supporting the implantation of the Prolift and Prolift+M  24 devices for pelvic organ prolapse."  25 What type of scientific evidence are you</p>	<p style="text-align: right;">Page 53</p> <p>1 literature, Prolift used the Gynemesh, which you  2 indicated had been on the market previously. What was  3 new was the concept of a product using the trocars and  4 deploying the mesh arms into muscle, connective tissue,  5 through the skin of the vagina and the external skin in  6 living people. That was a new concept. And I could not  7 find any information that there had been an objective  8 trial of that before the product was actually used.  9 Q. (BY MR. WEBB) Do you know whether or not --  10 when you say an objective trial, do you know what the  11 company had done as far as working with surgeons,  12 working with providing -- learning the techniques that  13 need to be used and teaching those techniques to  14 physicians prior to it being implemented for commercial  15 use?  16 MS. THOMPSON: Object to form.  17 A. What I understand or what I glean from the  18 literature is Dr. Jacquetin in France and Dr. Cossan,  19 C-O-S-S-A-N, and a group of French surgeons worked to  20 develop the concept of an American product being  21 deployed into the pelvis, and a lot of the original  22 observations were made with that French total vaginal  23 mesh group. So I did see that.  24 Q. (BY MR. WEBB) Well, do you know what kind of  25 protocols or what kind of scientific basis that the</p>

14 (Pages 50 to 53)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 54</p> <p>1 initial users of the product had or put in place before 2 they started using this product in patients? 3 MS. THOMPSON: Object to form. 4 A. What I know is they evaluate the patients for 5 prolapse in advance of surgery, what site in the pelvis 6 had poor support, and what degree of poor support that 7 those sites had. And they then looked at the technical 8 feasibility of placing the trocars into the pelvis and 9 deploying the mesh, and subsequently followed some of 10 the patients for a period of time to look at the 11 anatomic outcomes. 12 They then solicited opinions, 13 observations from clinicians on concerns about the 14 technical aspects of using the product, unknown concerns 15 that these physicians had heard from their patients 16 regarding either favorable or unfavorable outcomes from 17 the use of the product. 18 Q. (BY MR. WEBB) And is this, in your opinion, a 19 deviation from the norms in how you develop a new 20 product for use in patients? 21 MS. THOMPSON: Object to form. 22 A. Well, in this particular circumstance, 23 counseling a group of patients to participate in a 24 scientific trial and informing them of the risks and 25 benefits would be a helpful thing to do, understanding</p>	<p style="text-align: right;">Page 56</p> <p>1 them for -- in some cases, some of the earlier reports 2 were a matter of three to six months. Some were 3 perioperative injuries, some were one-year outcomes, 4 some were three-year outcomes. It's variable depending 5 on -- there were various stages of reporting. 6 Q. Do you know whether or not those patients have 7 been followed longer than that even though you haven't 8 seen any reports about it? 9 A. I'm not aware of it. By the time that the 10 product was available to be marketed, I'm not aware they 11 had been followed for a long enough time to provide 12 information so the surgeons and the patients could be 13 well informed about what to expect. 14 Q. You have an opinion that Prolift and Prolift+M 15 devices represent a significant departure from 16 traditional surgical procedures. What traditional 17 surgical procedures are you saying they are a 18 significant departure from? 19 A. Primarily various types of native tissue 20 repair. In some cases there had been reports on the use 21 of mesh in reconstructive surgery transvaginally, but 22 the early reports on mesh with transvaginal surgery did 23 not involve the use of a trocar. 24 The mesh either would have been placed 25 without a trocar, it may have been sutured in place --</p>
<p style="text-align: right;">Page 55</p> <p>1 that it's not possible to give full disclosure because 2 the trial is intended to learn about the potential 3 benefits and risks of the surgery. 4 So that would have been a helpful thing 5 to do. And then limiting the use of this product to a 6 defined group of people until there was adequate 7 information to make, if necessary, modifications in the 8 indications and use of the product to learn how to avoid 9 complications when possible and to learn how to manage 10 them if and when complications occur. 11 So that would have been an ideal set of 12 circumstances in a defined group of physicians and 13 surgeons and a defined group of patients, followed by a 14 long enough time period to be able to provide that 15 information. 16 Q. (BY MR. WEBB) Do you know whether or not the 17 patients in this initial group that were -- the French 18 surgeons used were provided -- what kind of informed 19 consent they were provided? 20 A. Some of them -- I don't know all of them. 21 Some of them actually were provided information that 22 they were collecting data on the -- on this technique. 23 Q. Do you know whether or not those physicians 24 followed these patients long term? 25 A. Well, initially they could only have followed</p>	<p style="text-align: right;">Page 57</p> <p>1 those are for the synthetic meshes. For the -- for the 2 synthetic permanent meshes. 3 For the absorbable meshes, those were 4 almost always applied as an applique. So the 5 traditional surgery -- excuse me -- was performed and 6 then, for lack of a better term, a patch of a synthetic 7 product was placed over that, and then the skin was 8 closed. But none of those required the use of trocars 9 to deploy the product. 10 Q. So the most significant departure that you're 11 identified for me is the use of a trocar? 12 MS. THOMPSON: Object to form. 13 Q. (BY MR. WEBB) Or use of trocars? 14 MS. THOMPSON: Object to form. 15 A. The significant deviation from what we were 16 accustomed to previously is deploying these arms into 17 muscle, connective tissue, and through the skin, and as 18 it turns out, really the only reasonable way to do that 19 is to use a trocar. 20 So the real deviation was having the mesh 21 arms through these tissue structures, and in order to 22 put them in those places, it was necessary to use a 23 trocar. 24 Q. (BY MR. WEBB) You say, "The vagina is a 25 different environment from the abdominal wall.</p>

15 (Pages 54 to 57)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 58</p> <p>1 Maintenance of vaginal compliance and distensibility is 2 essential for bowel, bladder, and sexual function." 3 Had there been a transvaginal surgery to 4 repair pelvic organ prolapse prior to the introduction 5 of Prolift and Prolift+M devices? 6 A. Excuse me. Historically, the most common way 7 to repair prolapse fell into two categories; one, 8 obliterate the vaginal canal; or, one -- or, two, 9 reconstruct the vaginal canal, ideally with a goal of 10 having some degree of normal size of the vaginal canal 11 and normal function of the bowel, bladder, and the 12 vagina as a sexual organ. 13 So obliteration of the vaginal canal is 14 an option in a very select subgroup of women, usually 15 not very many of them, but for some. And that normally 16 would only use suture materials, and that has been 17 described as long ago as approximately 1850. 18 Reconstructing the vaginal canal to try 19 to be more normal required a different level of 20 anesthesia, and surgery -- general anesthesia only 21 became safe in the mid to late 1800s. So reconstructive 22 surgery is limited by the ability to have safe either 23 regional or general anesthesia. So that began in the 24 late 1800s. 25 And for all practical purposes, that was</p>	<p style="text-align: right;">Page 60</p> <p>1 passage of trocars in deployment of a mesh arm, what 2 happens in this specific case is the trocars are passed 3 through tissue planes through which we normally never do 4 surgery, and those tissue planes of connective tissue 5 and muscle, primarily, have a vascular supply and a 6 nerve supply which is variable. 7 All anatomy is variable from one 8 individual to another, and when we pass these 9 instruments without being able to see where they are 10 going, we are using what we presume would be safe spots 11 to place the product, place the trocar. 12 And the potential dilemma with that is 13 that, in fact, for some people that may be a safe space 14 to put something. Surgery is very operator dependent. 15 And when I say "operator," I don't really mean surgeon. 16 I'm talking about whoever's doing it. It is very -- the 17 execution and the outcomes of surgery are dependent on 18 the technical execution of an operation. 19 So let's use a trocar, for example. I 20 don't have one here, but I have a pen. So when I'm 21 using something like this to either sew with or to put 22 into a tissue plane, I have the best control where I can 23 begin the use of the instrument and see it. If I'm 24 using a needle, for example, I have good control of 25 where that needle goes in, but where the needle comes</p>
<p style="text-align: right;">Page 59</p> <p>1 what was used unless a doctor took the patient's own 2 tissue, called fascia, to reinforce the repair. That 3 would be called an autologous repair. So that happened 4 in the early 1900s and later on during that century. 5 The concept of using mesh didn't really 6 take hold until -- in gynecology, for example, until 7 about the time a doctor in Wisconsin began -- he 8 reported on using mesh for the anterior compartment 9 without the use of trocars. Dr. Tom Julian did that, 10 and he noticed that in his evaluation of these women, 11 that anatomically they had improvement, but he also 12 noticed that there was an issue about erosion or 13 exposure of the vaginal mesh. 14 Q. You say that insertion of the mesh device 15 containing arms and involving the blind passage of 16 trocars presents specific risk and is inconsistent with 17 sound pelvic reconstructive surgical principles. Is 18 that correct? 19 A. Yes, sir. 20 Q. Is it -- if a surgeon chooses to use the 21 Prolift or Prolift+M in using blind passage of trocars, 22 is that below the standard of care if a surgeon chooses 23 to do that? 24 MS. THOMPSON: Object to form. 25 A. When a surgeon chooses to use the blind</p>	<p style="text-align: right;">Page 61</p> <p>1 out, the control isn't as predictable. 2 On a bigger scale, when you have 3 instruments that are curved, what happens is when you 4 think you are going into a particular plane, all the 5 movement out here exaggerates the movement at the end of 6 that instrument. So it's magnified. 7 So I think something is going in a 8 particular spot, but depending on how I manage this part 9 out here, that can deviate up or down or front or back, 10 and I don't have that good of control over it. So 11 that's one issue. 12 The second issue, the anatomy is 13 variable. So even if I go where I think a place is 14 safe, I can't see it, in fact. And you might ask, 15 "Well, how is that different than, let's say, a 16 suburethral sling, a midurethral sling, which uses a 17 trocar," which is a reasonable question. 18 With midurethral slings, we're operating 19 in spaces that surgeons, urologists, and gynecologists 20 have operated on for hundreds of years. And if you need 21 to see exactly what happened, you can make an incision 22 in the abdomen or use a kind of instrument and see 23 specifically where the trocar went or where the mesh 24 went. 25 You can't do that with these products</p>

16 (Pages 58 to 61)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 62</p> <p>1 that go through the muscles of the pelvis. Technically 2 it isn't possible to do that, so that's a big departure. 3 MR. WEBB: Objection, nonresponsive. 4 Q. (BY MR. WEBB) I was asking: Is it below the 5 standard of care for a surgeon to use Prolift or 6 Prolift+M with a procedure that is recommended for the 7 use of those products? 8 MS. THOMPSON: Object to form. 9 A. I don't think I said that in my general 10 report. I don't believe I indicated that. So the 11 answer is -- 12 Q. (BY MR. WEBB) So what you said in your 13 general report is insertion of a mesh device containing 14 arms involving the blind passage of trocars present 15 specific risk and is inconsistent with sound pelvic 16 reconstructive surgical principals. And if it's 17 inconsistent with sound pelvic reconstructive surgical 18 principals, is it below the standard of care for a 19 physician to do it? 20 A. I didn't say that. I said exactly what's 21 there. And in my opinion, I would not use these 22 products. Other people feel differently, that they can 23 safely use them, and the risks are less than the 24 benefit. 25 Q. Have you actually developed a medical device</p>	<p style="text-align: right;">Page 64</p> <p>1 don't agree with that, but I haven't submitted anything 2 for approval by a government agency. 3 Q. Do you know the process that any medical 4 device manufacturer goes through in order to get 5 approval, whether it be by the 510(k), or whether it be 6 by any other method to have a product approved? 7 A. I think I'm -- 8 MS. THOMPSON: Object to form. 9 A. I think I'm familiar with the 510(k) in that 10 the individual or the company who wants approval or 11 clearance through the 510(k) process is required to 12 provide certain documents, including is there a 13 predicate device, and was a predicate device cleared 14 before, and is the product that is being requested to 15 receive clearance similar to the predicate device. 16 And then there's a governmental agency 17 that makes a decision on that, yes or no. So I know 18 that part of the mechanism. 19 Q. (BY MR. WEBB) Do you consider yourself an 20 expert in that process? 21 MS. THOMPSON: Object to form, asked and 22 answered. 23 A. I'm conversant with it. I don't know what it 24 requires to be an expert about it. 25 Q. (BY MR. WEBB) Well, whether you're conversant</p>
<p style="text-align: right;">Page 63</p> <p>1 yourself and presented it to a company or developed it 2 yourself? 3 A. No, sir. 4 Q. Okay. Do you consider yourself an expert in 5 biomaterials? 6 A. From a -- excuse me. I'm losing my voice. 7 From a clinical standpoint, I feel I'm an 8 expert on evaluating people who have had biomaterials 9 put in. From a laboratory standpoint, have I looked at 10 these products under laboratory experimental conditions? 11 I haven't done that. 12 Q. Do you have any experience in the 13 manufacturing process of medical devices? 14 A. No, sir. 15 Q. Do you consider yourself an expert in 16 toxicology? 17 A. No, sir. 18 Q. Do you consider yourself an expert in 19 regulatory affairs or the FDA regulatory process 20 considering medical devices? 21 A. I consider myself knowledgeable about what we 22 are provided that meets the letter of the law, so I do 23 consider myself knowledgeable about that. 24 Now, whether I agree that that's all the 25 information we ought to have is a different issue, and I</p>	<p style="text-align: right;">Page 65</p> <p>1 or not, do you consider yourself an expert in that? 2 MS. THOMPSON: Object to form, asked and 3 answered. 4 A. Well, I don't know what you're asking me about 5 being an expert. I'm knowledgeable enough to know that 6 there is a process that has to take place and companies 7 are -- companies actually make their own decisions about 8 asking for 510(k) approval, if I'm not mistaken. And 9 then once they get in the system, there are parameters 10 that have to be provided, and then there is a government 11 agency group that either asks for clarification on the 12 information that's been requested, which has happened 13 with Ethicon and J&amp;J, and then the company has an 14 opportunity to respond to that and can -- they come to a 15 consensus on what is the adequate amount of information 16 that's necessary before approval is given. 17 So I know those aspects of how -- 18 Q. (BY MR. WEBB) Have you ever served on an FDA 19 approval panel? 20 A. No, sir. 21 Q. Have you ever testified or been asked to give 22 expert testimony in front of an FDA panel? 23 A. No, sir. Excuse me. No, sir. 24 Q. Do you know what the standard is by which the 25 FDA will either approve or disapprove of any medical</p>

17 (Pages 62 to 65)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 66</p> <p>1 device that's submitted for approval?</p> <p>2 MS. THOMPSON: Object to form.</p> <p>3 A. Well, in the case of a new product, they would</p> <p>4 require information about the technical -- let's use</p> <p>5 something in the pelvis, for example -- about the</p> <p>6 technical qualities, the description of what it is, what</p> <p>7 its intended purposes are, and if it -- if we have</p> <p>8 information about how this, in this case, product</p> <p>9 behaves in the laboratory, for example.</p> <p>10 If they're -- if you're requesting based</p> <p>11 on similarity to a predicate product, then the person</p> <p>12 requesting clearance has to say that their newer product</p> <p>13 is substantially equivalent from the predicate device</p> <p>14 that was previously approved and provide the information</p> <p>15 to document that.</p> <p>16 Q. (BY MR. WEBB) You talked a little bit about</p> <p>17 the process. You didn't tell me what the standard is</p> <p>18 that the FDA looks at.</p> <p>19 MS. THOMPSON: Object to form.</p> <p>20 A. I don't know that I can articulate the</p> <p>21 standard.</p> <p>22 Q. (BY MR. WEBB) Have you ever studied the</p> <p>23 properties of polypropylene mesh in the laboratory?</p> <p>24 A. No, sir.</p> <p>25 Q. Have you ever looked at any mesh, Prolift or</p>	<p style="text-align: right;">Page 68</p> <p>1 sling myself and I may later operate on the woman</p> <p>2 because she has a reason for reoperation. Excuse me.</p> <p>3 In identifying the sling product, I can,</p> <p>4 in that circumstance, make the observation that that</p> <p>5 sling is more tightly applied than it was when I did the</p> <p>6 surgery previously, if that surgery was a week ago or</p> <p>7 years ago, which could have been the case, that it</p> <p>8 doesn't have the same freedom of lack of tension that it</p> <p>9 had when it was originally placed.</p> <p>10 And then the presumption would be that</p> <p>11 that is -- that the mesh is -- the dimensions are</p> <p>12 getting smaller through the wound healing, scar</p> <p>13 formation, or some intrinsic product -- some intrinsic</p> <p>14 characteristic of the product itself.</p> <p>15 Q. Do you --</p> <p>16 A. So I have seen that in my own patients.</p> <p>17 Q. Using a -- what is generally considered to be</p> <p>18 a cure rate of -- for surgeons in your practice, what</p> <p>19 would you say the cure rate is, roughly, for the</p> <p>20 patients that you have used polypropylene mesh in for</p> <p>21 the years that you've been practicing and using that</p> <p>22 mesh?</p> <p>23 MS. THOMPSON: Object to form.</p> <p>24 A. For the treat -- excuse me. For the treatment</p> <p>25 of urinary incontinence?</p>
<p style="text-align: right;">Page 67</p> <p>1 Prolift+M, under a microscope, even?</p> <p>2 A. No, sir.</p> <p>3 Q. Ever done any degradation testing on</p> <p>4 polypropylene mesh?</p> <p>5 A. Excuse me. No, sir.</p> <p>6 Q. Any elasticity studies?</p> <p>7 A. In that standpoint, only in the clinical</p> <p>8 aspects of palpating products that have been placed in</p> <p>9 someone in making my own clinical assessment of whether</p> <p>10 or not those tissues are tightly stretched out or not.</p> <p>11 So from a clinical standpoint, I've done that.</p> <p>12 Q. Have you ever quantified that, or is that a</p> <p>13 subjective test according to your --</p> <p>14 A. I'm not aware there's a -- with the exception</p> <p>15 of looking at ultrasound, which, actually, I don't think</p> <p>16 measures elasticity anyway, there is not an objective</p> <p>17 way -- all the other reports I'm familiar with are a</p> <p>18 clinical assessment.</p> <p>19 Q. Have you ever done any shrinkage studies to</p> <p>20 see -- personally done any shrinkage studies to see if</p> <p>21 there's any shrinkage of polypropylene mesh?</p> <p>22 A. Not in the laboratory. Again, I would rely on</p> <p>23 my clinical observations. And one of the ways that I</p> <p>24 have observed clinically about shrinkage is in the case</p> <p>25 of midurethral slings where I, in fact, have placed the</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. (BY MR. WEBB) Yes, sir.</p> <p>2 A. Yes, sir. My observation is from the time I</p> <p>3 began my work in 1975 where I am right now, until about</p> <p>4 2001 or '2, so that would have been 25 years, more or</p> <p>5 less, I did surgery for urinary incontinence using</p> <p>6 native tissue only.</p> <p>7 And the clinical outcomes of the patients</p> <p>8 that I used native tissue for compared to the women in</p> <p>9 whom I used the midurethral sling following 2000 and</p> <p>10 2001 -- that became my operation I did more</p> <p>11 frequently -- I would say the absence of symptoms of</p> <p>12 incontinence were similar with both of those, so -- in</p> <p>13 everybody who's tested it.</p> <p>14 So I haven't reported on that. But the</p> <p>15 people who do report on it, the conclusions are that the</p> <p>16 outcomes of cure of incontinence are very similar with</p> <p>17 the synthetic midurethral sling as with the previous</p> <p>18 operations which didn't require sling material. So I</p> <p>19 think there is a consensus about that.</p> <p>20 Q. And what is the percentage that you would say?</p> <p>21 A. It's -- it's time related. So the earlier</p> <p>22 after the procedure the patient is evaluated, the more</p> <p>23 likely they're to be cured. And the cure rate is a</p> <p>24 function of time, so the longer you follow someone, the</p> <p>25 cure rate has a certain deterioration every year.</p>

18 (Pages 66 to 69)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 70</p> <p>1 But in the first year or so, the patients 2 are counseled that approximately 80 percent are going to 3 be satisfied with bladder control, coughing, laughing, 4 straining, and sneezing. 5 Depending on how stringent the 6 requirements are for objective proof, the cure rate 7 isn't that high. But practically speaking, most doctors 8 are going to use the patient satisfaction issue, and 9 about 80 or 85 percent are going satisfied. 10 Q. Have you ever followed a patient who had a 11 Prolift product in order to quantify any shrinkage or 12 degradation or anything that you would follow over a 13 long period of time? 14 A. I think there are several groups of patients. 15 I have seen some patients, and I believe they've had 16 Prolift, but if you ask me to prove that, I don't -- 17 can't prove it today. But I have seen patients who had, 18 for example, posterior Prolift, who have come to me for 19 concerns about pain in the vaginal canal or pain with 20 bowel function because the mesh itself isn't 21 distensible, and when their bowel works, the mesh can 22 create a delay in bowel emptying. 23 So in some of those women, I've examined 24 them and said, yes, I think this product has more 25 tension on it than was ever intended, but I didn't put</p>	<p style="text-align: right;">Page 72</p> <p>1 pathologists haven't. Now, it's possible that some of 2 the patients that I've operated on have had specimens 3 sent elsewhere for evaluation. 4 Because periodically what will happen, 5 I'll operate on someone to revise or explant graft 6 material, and the request from the patient and her legal 7 counsel is to forward that tissue on to someone else, in 8 which case I don't think I ever received a report on 9 that. We follow their request and submit it to someone, 10 but I'm not in the loop where I would get a report back 11 to observe that. 12 Q. Are you aware of any studies in the medical 13 literature in the 2000 to 2005 timeframe that found good 14 results with the use of transvaginal mesh kits? 15 A. I'll have to look specifically about -- about 16 the year. Just a moment. 17 The -- did you ask me mesh kit? Is that 18 what you asked me, or mesh? 19 Q. Mesh kits. 20 A. Mesh kit. I don't remember what -- excuse 21 me -- in that timeframe, and when I look -- excuse me. 22 When I look in the bibliography of an 23 article by a Dr. Jacquetin, who developed Prolift -- and 24 this is a report in 2009 on the total vaginal mesh 25 technique. When I look at his bibliography, I don't see</p>
<p style="text-align: right;">Page 71</p> <p>1 it in, and I suspect it's tighter than it was before. 2 And the patient may choose not to have anything done, 3 and I may see her back for evaluation later, and she 4 still may not have symptoms for her that warrant another 5 operation. So I've seen people like that. 6 I've seen some people who have had 7 anterior Prolift, and they don't have a complaint about 8 anything. They want to be seen, frankly, because 9 they're curious, is there something the matter with me 10 because I've had this product. And I may examine them, 11 and I may say, "No. I think presently you're okay," and 12 I wouldn't do anything, and I would -- just be followed 13 periodically. 14 So there's a subset of people who, for 15 all practical purposes, when I've seen them are 16 clinically doing well, and there's no reason to 17 recommend doing anything. 18 Q. Have you ever personally observed any 19 degradation of any Prolift product? 20 A. Well, that's a microscopic diagnosis, and the 21 answer is no. 22 Q. Has anybody ever reported to you when you sent 23 something to a pathologist of any degradation of any 24 Prolift product? 25 A. You know, on my specific patients, our</p>	<p style="text-align: right;">Page 73</p> <p>1 any reference to something published using a mesh kit 2 during that time period from 2000 to 2005. He 3 referenced Dr. Julian, whom I spoke about earlier, and 4 that article was -- was reported in 1996, and it was a 5 mesh applique. 6 So I don't know about reports on the mesh 7 kit before 2005. 8 Q. How did you reach the conclusion that Ethicon 9 did not provide doctors and patients with complete and 10 accurate information regarding the complications 11 associated with Prolift and Prolift+M devices and their 12 management? 13 A. Because some of the information we only learn 14 as time goes by about long-term outcomes. That's a 15 variety of things that we do. And I'll use abdominal 16 sacrocolpopexy, which has been an operation around since 17 1950 or so. 18 Some of the concerns about abdominal 19 sacrocolpopexy in terms of mesh erosion or exposure only 20 are evident years after the original repair or some of 21 the other complications regarding adhesion and bowel 22 perforation. So we know from another pelvic 23 reconstructive procedure that the true story unfolds 24 over a time period. 25 And the reason I don't think people were</p>

19 (Pages 70 to 73)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 74</p> <p>1 provided adequate information is, one, there wasn't 2 enough time to go by to find out have we seen the bulk 3 of these issues or what is the natural history of these 4 women? That's one thing. 5 And then the second thing is it isn't 6 clear that that objective of some of these early studies 7 was really to look at, for example, quality of life or 8 effects on pain or sexual function. The early studies 9 were primarily on anatomical outcomes and the 10 perioperative morbidity. And that's why I think it 11 would be hard for me to counsel someone based on the 12 information that was available in 2004 or '5 or '6 or 13 '7. The information just wasn't available. 14 Q. Well, it's not that Ethicon held it back. 15 It's just that it wasn't available. Is that what you're 16 saying? 17 A. Well -- 18 MS. THOMPSON: Object to form. 19 A. Well, certain information clearly wasn't 20 available, and then whether or not there was 21 knowledge -- and there was knowledge about some of the 22 things regarding exposure rate and pain, for example. 23 It's hard -- you can say that someone has pain, for 24 example, and that can be disclosed in the information 25 for use document, but it doesn't necessarily go into</p>	<p style="text-align: right;">Page 76</p> <p>1 organ prolapse, a three-year prospective follow-up 2 study." 3 Dr. Jacquetin and his colleagues were and 4 are the most knowledgeable about the technical aspects 5 of the procedure, and I would presume they are very 6 knowledgeable about patient selection. 7 So this is the group who conceived of the 8 idea, who have the most skill associated with it, and at 9 three years after surgery, one out of five women had an 10 anatomical failure rate, and one out of seven had mesh 11 exposure. 12 So when I say "benefit," the benefit is 13 80 percent of people got better, 20 percent had an 14 anatomical failure. That's not appreciably different 15 than someone who had native tissue surgery. 16 I reported on my own experience 17 previously, ten years before that, using native tissue, 18 and there's no appreciable benefit to -- in my patients 19 to using the product when you look at anatomical 20 outcomes, for example. And I didn't have one out of 21 seven patients with mesh exposure. 22 So that's what I mean when I say I don't 23 think patients were fully informed of the benefit. So 24 you might -- if you ask me specific benefits, besides 25 anatomy, then I'll try to respond to that. But in the</p>
<p style="text-align: right;">Page 75</p> <p>1 detail about the severity of the pain, how frequently it 2 occurs, and how long it occurs. 3 So I could say that, well, I knew there 4 could be pain associated with it, and maybe the patient 5 knew there was pain, but in my opinion, that isn't the 6 full extent of what someone would want to know about the 7 outcome of surgery. I don't think we had all the 8 information. 9 Q. You don't think Ethicon had all that 10 information? 11 A. I don't think that -- 12 MS. THOMPSON: Object to form. 13 A. I don't think they had all of it, because not 14 all of the trials were designed to collect that 15 information. Plus not enough time had gone by. 16 Q. (BY MR. WEBB) You say Ethicon failed to 17 disclose the lack of benefit of pelvic organ prolapse 18 surgery using Prolift and Prolift+M devices to 19 physicians and patients. 20 What do you base that opinion on? 21 A. Well -- excuse me. Again, it's a question of 22 time and how you report the information. 23 I'll give you an example. This article 24 by Dr. Jacquetin published in 2010 was called, "Total 25 transvaginal mesh technique for treatment of pelvic</p>	<p style="text-align: right;">Page 77</p> <p>1 absence of that, these trials, these reports are based 2 primarily on anatomy. 3 And that was the concept to begin with. 4 Surgery doesn't have as good an anatomic outcome as it 5 should; i.e., we need to do something different to try 6 to improve it. 7 Q. Your opinion that removal of mesh is always a 8 complex surgery, is it your personal experience that 9 every removal surgery is complex? 10 A. It can be. I think you have to be aware of 11 that. Now, again, I'll say surgery is like every job. 12 Sometimes you start the job, and technically it's easier 13 than what you anticipate, but sometimes the converse of 14 that is true. You think this will be not particularly 15 difficult, and it actually is. 16 So you have to be prepared that it can be 17 difficult, and, in fact, some of the explant procedures 18 are technically very challenging. Not all of them are. 19 Q. What's your basis for saying that Ethicon 20 lacks scientific rigor in testing and reporting of its 21 pelvic floor products? 22 A. I think I've alluded to it before. Under a 23 circumstance which would have been better is there would 24 have been, sequentially, the concept of what ought to be 25 done, and after the concept, then is it practical to do</p>

20 (Pages 74 to 77)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 78</p> <p>1 what conceptually you have in mind to do.</p> <p>2 And if what you want to do has a proposed</p> <p>3 benefit, you have to be very clear about what that</p> <p>4 benefit is as well as articulating what the possible</p> <p>5 risk could be. So if you do this, whatever it is, have</p> <p>6 in mind what -- the possible adverse events that could</p> <p>7 occur, and we need to monitor those.</p> <p>8 And then in order to say, "I'll use this</p> <p>9 group of Dr. Jacquetin" -- and I'm using him because</p> <p>10 he's knowledgeable about this. So if Dr. Jacquetin has</p> <p>11 worked on a way to have better outcomes from surgery,</p> <p>12 the real way to know that is he would have to compare</p> <p>13 this innovation to what he was previously doing in a</p> <p>14 fashion that is ideally not biased, and then in a period</p> <p>15 of time he could look at that and say they're equal or</p> <p>16 they aren't equal, and they're not equal for whatever</p> <p>17 the reasons are. I don't see that as having transpired.</p> <p>18 I see it as having recruited a number of</p> <p>19 women to undergo a procedure and then make longitudinal</p> <p>20 observations about them as opposed to comparing it with</p> <p>21 something done, which under ideal circumstances is how</p> <p>22 it would work.</p> <p>23 Q. So this is another one of your opinions that</p> <p>24 criticizes the lack of a clinical study with the</p> <p>25 parameters that you would expect to have in a clinical</p>	<p style="text-align: right;">Page 80</p> <p>1 protocol, and patients were informed they were in a</p> <p>2 trial to try to learn the best way to effect the</p> <p>3 procedure, to minimize pain, and minimize urinary</p> <p>4 leak -- urinary infections.</p> <p>5 Q. So they were approved by your Institutional</p> <p>6 Review Board?</p> <p>7 A. Yes, sir.</p> <p>8 Q. Were they approved by the FDA?</p> <p>9 A. No, sir.</p> <p>10 MS. THOMPSON: Object to form.</p> <p>11 A. No, sir.</p> <p>12 Q. (BY MR. WEBB) Were they ever submitted to the</p> <p>13 FDA?</p> <p>14 A. No, sir. It wasn't required.</p> <p>15 Q. Did you ever -- do you know whether or not any</p> <p>16 of the testing done by any of the doctors using Prolift</p> <p>17 or Prolift+M was approved by Institutional Review</p> <p>18 Boards?</p> <p>19 A. Yes, sir, I do. In France, I believe that</p> <p>20 some of those were approved. And some of those that</p> <p>21 were multicenter. I'm not sure that every center in</p> <p>22 every country required that, but, yes, I know for a fact</p> <p>23 some of them were.</p> <p>24 Q. Do you know whether or not they were approved</p> <p>25 by the regulatory bodies in the individual countries?</p>
<p style="text-align: right;">Page 79</p> <p>1 study. And because of the critique that you have, you</p> <p>2 feel that Ethicon failed to do proper studies to show</p> <p>3 the safety and the effect -- the efficiency or the</p> <p>4 efficacy of this product?</p> <p>5 A. Yes, sir.</p> <p>6 Q. Have you personally ever put together a</p> <p>7 scientific clinical study that has been used for any</p> <p>8 medical device or any drug?</p> <p>9 A. The one -- excuse me. We have done two</p> <p>10 relating to the Gynecare TVT. And one of them was in an</p> <p>11 effort to minimize the likelihood of getting a bladder</p> <p>12 infection following the procedure. We had a randomized</p> <p>13 trial where women who were going to undergo a TVT were</p> <p>14 either given an antibiotic for a defined time period or</p> <p>15 not.</p> <p>16 And then we had another with a retropubic</p> <p>17 sling, looking at injecting the retropubic space with</p> <p>18 what's called hydrodissection -- that's part of the</p> <p>19 IFU -- with hydrodissection with the use of saline</p> <p>20 versus the use of a local anesthetic agent to see if</p> <p>21 that affected the amount of pain medication that a</p> <p>22 patient would need in the recovery period.</p> <p>23 So we didn't design a product. We did</p> <p>24 look at two randomized trials where patients were</p> <p>25 approved -- the Institutional Review Board approved the</p>	<p style="text-align: right;">Page 81</p> <p>1 MS. THOMPSON: Object to form.</p> <p>2 A. No, sir, I don't know that.</p> <p>3 Q. (BY MR. WEBB) The two randomized studies that</p> <p>4 you -- or trials that you worked on, did you publish the</p> <p>5 results of those trials?</p> <p>6 A. Yes, sir.</p> <p>7 Q. And were they submitted to a scientific</p> <p>8 journal or a medical literature journal?</p> <p>9 A. Yes, sir. They were presented in a scientific</p> <p>10 meeting, and the authors were fellows of ours, and the</p> <p>11 one on antibiotics was a multicenter one with a group</p> <p>12 from the University of Missouri, as well as from us, and</p> <p>13 the one on the local anesthetic was in our organization</p> <p>14 only.</p> <p>15 Q. Was it a poster presentation? Was it an</p> <p>16 abstract? Was it actually an article submitted to</p> <p>17 peer-reviewed literature and published?</p> <p>18 A. I know for a fact one of them was an oral</p> <p>19 presentation. The one that had the primary author from</p> <p>20 the University of Missouri, I don't know if that was</p> <p>21 oral, but it's been published. And the one that</p> <p>22 Dr. Jessica Bracken did, who works in our organization,</p> <p>23 presented it, and to the best of my knowledge it's</p> <p>24 published, but I can confirm that if you give me -- at</p> <p>25 least -- it may not be in my CV, but she's the primary</p>

21 (Pages 78 to 81)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 82</p> <p>1 author for it.</p> <p>2 Q. You have some criticism in Opinion No. 13 that</p> <p>3 Ethicon did not exercise due diligence in the design and</p> <p>4 development of Prolift and Prolift+M devices.</p> <p>5 Have you ever designed or developed any</p> <p>6 medical device yourself?</p> <p>7 A. Excuse me. No, sir.</p> <p>8 Q. Did you ask for and receive all the Ethicon</p> <p>9 documents that referred to the design and development of</p> <p>10 the Prolift and Prolift+M devices?</p> <p>11 A. I didn't ask for them. I doubt seriously I</p> <p>12 received all of them.</p> <p>13 Q. In the half banker box of documents that we</p> <p>14 have that are sitting here on the table that you were</p> <p>15 provided by plaintiffs' counsel, did you see any</p> <p>16 documents in there related to the design and development</p> <p>17 of the Prolift and Prolift+M devices?</p> <p>18 MS. THOMPSON: Object to form.</p> <p>19 A. No, sir.</p> <p>20 Q. (BY MR. WEBB) What's the basis, then, of your</p> <p>21 opinion that Ethicon did not exercise due diligence in</p> <p>22 the design and development of the Prolift and Prolift+M</p> <p>23 devices?</p> <p>24 A. The clinical outcomes. The patients --</p> <p>25 patients have been harmed.</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. (BY MR. WEBB) Do you know if the FDA has ever</p> <p>2 requested that Prolift or Prolift+M be removed from the</p> <p>3 market because they were not safe or effective for their</p> <p>4 intended use?</p> <p>5 MS. THOMPSON: Object to form.</p> <p>6 A. What I know is that the FDA hasn't removed --</p> <p>7 not only their products, the other products -- but the</p> <p>8 products -- most of the products are no longer sold.</p> <p>9 And the companies have made that decision themselves.</p> <p>10 So the FDA wasn't obliged to make that decision.</p> <p>11 Q. (BY MR. WEBB) Well, the question I asked you:</p> <p>12 Has the FDA ever said that the Prolift or Prolift+M</p> <p>13 products are neither safe or effective and must be</p> <p>14 removed from the market?</p> <p>15 MS. THOMPSON: Object to form.</p> <p>16 A. What the FDA has said is that the companies</p> <p>17 will continue to make the products. There's a different</p> <p>18 level of documentation that has to be submitted,</p> <p>19 including further trials of safety and efficacy, and for</p> <p>20 some product for some companies, they're attempting to</p> <p>21 do that.</p> <p>22 For other products, including these</p> <p>23 products, that hasn't been done, and the products aren't</p> <p>24 available. But the FDA didn't take them off the market.</p> <p>25 The company chose to quit selling them.</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. You understand that the FDA has required as</p> <p>2 its standard that a medical device must be safe and</p> <p>3 efficient -- it needs to be effective -- safe and</p> <p>4 effectively for its intended use. Do you understand</p> <p>5 that?</p> <p>6 MS. THOMPSON: Object to form.</p> <p>7 A. I know that -- excuse me. I know there are</p> <p>8 different levels of clearance for approval for products,</p> <p>9 and some require a lesser amount of documentation than</p> <p>10 others.</p> <p>11 And initially, the 510(k) for these</p> <p>12 products required a lower level of substantiating</p> <p>13 information than is currently being requested by the</p> <p>14 FDA.</p> <p>15 Q. (BY MR. WEBB) In order for a medical device</p> <p>16 to remain on the market, it must be safe and effective</p> <p>17 for its intended use. Correct?</p> <p>18 MS. THOMPSON: Object to form.</p> <p>19 A. I don't know the answer to that.</p> <p>20 Q. (BY MR. WEBB) Would you agree that if the FDA</p> <p>21 feels that a medical device is neither safe nor</p> <p>22 effective -- not safe or not effective, that it should</p> <p>23 be removed from the market?</p> <p>24 MS. THOMPSON: Object to form.</p> <p>25 A. I would presume that would be the case.</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. (BY MR. WEBB) You say that the -- Ethicon did</p> <p>2 not heed the warnings from the hernia and gynecologic</p> <p>3 literature regarding the use of polypropylene mesh.</p> <p>4 What are you talking about there?</p> <p>5 A. Well, in hernia repair, which is what my</p> <p>6 report is generally about, there have been warnings</p> <p>7 about using a synthetic product in an infected wound,</p> <p>8 for example. So let's use the case of abdominal or</p> <p>9 inguinal hernia repair, general surgical principles,</p> <p>10 which we referred to earlier, would say that you</p> <p>11 wouldn't put a synthetic product in an infected wound.</p> <p>12 The vagina -- the vaginal canal is never</p> <p>13 sterile. It's what's referred to in medical terms as a</p> <p>14 clean contaminated field. So a hernia surgery isn't in</p> <p>15 a sterile field. A vaginal surgery is in a clean</p> <p>16 contaminated field.</p> <p>17 There was evidence in other literature</p> <p>18 that -- in the general surgery literature and the</p> <p>19 pathologic literature that mesh, in fact, does contract</p> <p>20 in animal models as well as in humans when used for</p> <p>21 hernia surgery, and there are people who had pain</p> <p>22 complaints.</p> <p>23 So when -- this specific reference that</p> <p>24 you gave that I have in my general report is, in my</p> <p>25 opinion, those issues weren't adequately addressed</p>

22 (Pages 82 to 85)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 86</p> <p>1 before the company marketed a product -- synthetic 2 polypropylene mesh to put in a clean contaminated field, 3 which is what the vaginal canal is. 4 In some of the articles in the folder 5 which I have given you -- and I'd have to look them 6 up -- that issue is actually highlighted, the vaginal 7 canal is not the abdominal cavity or abdominal wall, 8 either one. 9 Q. Ethicon inappropriately marketed the Prolift 10 and Prolift+M products to all physicians and did not 11 properly train these physicians in the unique aspects of 12 patient selection and patient counseling of long-term 13 sequelae of trocar-based mesh kits. 14 Does a company like Ethicon have the 15 right to tell a physician they cannot use a medical 16 device that's been approved by the FDA? 17 MS. THOMPSON: Object to form. 18 A. My -- my reasoning for that comment is in the 19 Ethicon study group, the transvaginal mesh group, highly 20 educated, highly skilled, highly experienced with a 21 level of complications I've already referred to, 22 20 percent failure rate at three years, one out of seven 23 with mesh exposure, and these were people who had 24 extensive experience in monitoring. 25 When the product was available for sale,</p>	<p style="text-align: right;">Page 88</p> <p>1 MS. THOMPSON: Asked and answered. 2 A. Well, you're asking, I think, a hypothetical 3 situation, that could the company do it or is it legal. 4 I mean, I think those are two separate issues. Could 5 the company do it, and then when the physician or 6 physicians say, then, "You're restraining my practice of 7 medicine," and then it becomes a legal issue about 8 that -- I suspect that's probably what would happen. 9 I don't -- when you ask me can Ethicon do 10 that, I don't know the legal requirements for that. 11 Q. (BY MR. WEBB) You expressed an opinion that 12 said that Ethicon inappropriately marketed the Prolift 13 and Prolift+M products to all physicians. 14 Does Ethicon have the right to deny the 15 use of their products by a properly licensed physician? 16 MS. THOMPSON: Object to form, asked and 17 answered. 18 A. I think there's -- that's not a binary 19 question. There is nothing that I know of that says 20 there's a minimum skill set required to use this 21 product. That would be a reasonable thing to have done, 22 to say, "In order to use this properly, you should have 23 this amount of knowledge to use the product I am making 24 and use it successfully." 25 That's an opinion. So you asked my</p>
<p style="text-align: right;">Page 87</p> <p>1 physicians could request training if they wanted it, and 2 Ethicon may provide it. 3 Is it reasonable based on the knowledge 4 that was obtained from the early studies to say that 5 someone should have training before a product is used? 6 In my opinion, that's a reasonable thing to do, because 7 the truth is not everyone is equally capable of doing 8 these procedures, and, in general, when people who are 9 advocates of using this particular mesh product comment 10 on complications, one of the variables that's pointed 11 out is the surgeon's technical skills are involved in 12 the complication. 13 MR. WEBB: Objection, nonresponsive. 14 Q. (BY MR. WEBB) The question I asked you: Does 15 Ethicon have the right or ability to tell a physician 16 they cannot use a product that's been approved by the 17 FDA? 18 MS. THOMPSON: Object to form. 19 A. I don't know that they would. I'm sure they 20 could. 21 Q. (BY MR. WEBB) So your testimony is that a 22 company could tell a physician that they cannot use an 23 approved medical device, even if they refuse training, 24 that they're using it inappropriately, but a company 25 like Ethicon could refuse to sell to that physician?</p>	<p style="text-align: right;">Page 89</p> <p>1 opinion, and that's mine. 2 Q. (BY MR. WEBB) Okay. And so what's the basis 3 of that opinion? 4 A. Patient safety. 5 Q. If a physician refuses to be trained in the 6 unique aspects of patient selection, patient counseling, 7 is there anything that Ethicon can do if they refuse to 8 be trained in the use of the products? 9 MS. THOMPSON: Object to form. 10 A. I don't know the -- excuse me. I don't know 11 legally if Ethicon could do anything about that or not. 12 Ethicon, by the way, doesn't sell to individuals, I 13 don't believe. I think they sell to hospitals, but I 14 may be wrong about that. 15 In our case, the hospital buys the 16 product, because it's a hospital-based procedure. In 17 other areas, it's possible that individual physicians 18 can purchase it, but I don't know that. 19 Q. (BY MR. WEBB) Well, how in the world is 20 Ethicon even supposed to know the level of expertise or 21 competence of physicians if they're selling it to the 22 hospital, whether or not those hospitals are allowing 23 physicians who are not competent to use the product? 24 MS. THOMPSON: Object to form. 25 A. I don't know the answer to that.</p>

23 (Pages 86 to 89)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 90</p> <p>1 Q. (BY MR. WEBB) Is it your opinion that Ethicon 2 did not have a system in place to monitor their product 3 or evaluate physician feedback on the products? 4 A. If they had one, it wasn't obvious to the 5 physicians who were using the products. 6 Q. Do you know whether or not the FDA requires 7 that there be adverse event monitoring on all approved 8 medical devices? 9 MS. THOMPSON: Object to form. 10 A. There is the MAUDE database which people can 11 use. I don't know that the FDA can require a physician 12 to report adverse effects. 13 MR. WEBB: Nonresponsive. Objection; 14 nonresponsive. 15 THE WITNESS: I'm sorry. I didn't 16 understand your question. 17 Q. (BY MR. WEBB) Does the FDA require that there 18 be an adverse event database maintained for any approved 19 medical device? 20 MS. THOMPSON: Object to form. 21 A. I believe that depends on the level at which 22 the device -- in terms of the potential injury, you 23 know, Level 1, 2, or 3. 24 So the greater the potential for risk, 25 then there may be a requirement for that, but I don't</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. (BY MR. WEBB) There's also sales literature, 2 and there's also, sometimes, videos or CDs? 3 A. Yes, sir, there frequently are. 4 Q. In your expert report, there's a section about 5 examples of Ethicon documents supporting these opinions. 6 Are all these Ethicon documents that you have placed in 7 the report, are they documents that were provided to you 8 by plaintiffs' counsel and came out of the banker box 9 that we have here? 10 A. Yes. Excuse me. Yes, sir. 11 Q. Okay. And as you read through those 12 documents, did you request other documents because you 13 saw something referenced and you wanted to see if there 14 was any follow-up? For example, if there was an email 15 chain, did you ask what happened after this issue was 16 raised? 17 A. To the best of my knowledge -- excuse me -- I 18 did not do that. 19 Q. In one of the Ethicon documents they report 20 that Professor Jacquetin is the inventor of the pelvic 21 floor repair technique Gynecare will be marketing this 22 year. 23 Do you know whether Ethicon worked with 24 Dr. Jacquetin or whether it was something he came up 25 with on his own and then approached the company?</p>
<p style="text-align: right;">Page 91</p> <p>1 know that for sure. 2 Q. (BY MR. WEBB) In any of the Ethicon devices 3 that you use in your practice, did you receive training 4 by any sales personnel? 5 A. No, sir. I saw the products demoed at 6 meetings, but there wasn't a non-physician 7 representative teaching me how to use the product, if 8 that's your question. 9 Q. They were demonstrated at medical meetings by 10 other physicians who were using the product? 11 MS. THOMPSON: Object to form. 12 A. That's one way. And then at the medical 13 meetings, at the scientific exhibits and the commercial 14 exhibits, various companies, regardless of what they're 15 selling, will have part of their sales force present to 16 inform people about what they're selling, and they may 17 or may not have a physician available to talk about the 18 physician aspects of it. 19 So early on in the introduction of the 20 retropubic slings, for example, it was common at 21 meetings to have a physician or more than one physician 22 present discussing the use of a product, and it would be 23 common to have a representative of the company there to 24 answer questions or to ask if you needed more 25 information, publications and whatnot.</p>	<p style="text-align: right;">Page 93</p> <p>1 MS. THOMPSON: Object to form. 2 A. I don't know that for a fact. I know him, and 3 I was present when he did one of these mesh kit 4 procedures in Italy before the product was commercially 5 available because he and I were doing live surgery at a 6 surgical course outside of Milan, Italy. 7 And I know that he worked with his group 8 on the concept, but I don't -- to the best of my 9 knowledge, Ethicon or J&amp;J did not approach him to 10 develop a concept, if that's the question. I believe 11 the idea was his and his group. 12 Q. (BY MR. WEBB) Some of the documents you 13 reviewed are actually presentations that were made 14 either in-house or externally by Ethicon. Is that 15 correct? 16 A. Yes, sir. 17 Q. And you've identified some of the problems 18 that they were discussing both internally and what they 19 were discussing in -- outside the company in some of 20 these documents that you've included in your report. 21 Correct? 22 A. Yes. Excuse me. Yes, sir. 23 Q. Will you agree with the concept that on any 24 medical device, the longer it's in use, the more we 25 understand both the risks and benefits of any medical</p>

24 (Pages 90 to 93)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 94</p> <p>1 device?</p> <p>2 MS. THOMPSON: Object to form.</p> <p>3 A. I would say generally that's true.</p> <p>4 Q. (BY MR. WEBB) Have you talked -- or read any</p> <p>5 depositions in which the documents that you have</p> <p>6 included, the Ethicon documents you included in your</p> <p>7 expert report are discussed or explained?</p> <p>8 A. I don't believe I have. Excuse me. I don't</p> <p>9 think so.</p> <p>10 Q. On some of these documents, did you just take</p> <p>11 portions of the document to include it in your expert</p> <p>12 report?</p> <p>13 A. I'm sorry. I don't -- can you give me an</p> <p>14 example of that?</p> <p>15 Q. For example, if you go to Page 44 of your</p> <p>16 report.</p> <p>17 A. I gave you my only copy of the report. I'm</p> <p>18 sorry.</p> <p>19 Q. Okay. Did you take out paragraphs or excerpts</p> <p>20 sometimes in order to make the point that you wanted to</p> <p>21 make but didn't include the entire document?</p> <p>22 A. I'm sure that's possible that I did.</p> <p>23 Q. Were you aware that in some of your past</p> <p>24 general reports, some of your opinions have been</p> <p>25 excluded by the federal court for various reasons?</p>	<p style="text-align: right;">Page 96</p> <p>1 know a lot about pelvic surgery because that's what I</p> <p>2 do.</p> <p>3 So I know a lot about it, and other</p> <p>4 people recognize that because I see people and offer</p> <p>5 them options for non-surgical, medical, or surgical</p> <p>6 therapy, and I follow them up. And I've seen people who</p> <p>7 have been treated with various other surgical techniques</p> <p>8 that I may not personally use, and not all of them are</p> <p>9 patients who have a problem.</p> <p>10 But the truth is I do see women who have</p> <p>11 had problems, and I feel, as an experienced,</p> <p>12 knowledgeable person, that I am more knowledgeable than</p> <p>13 the average person doing pelvic surgery. That's what</p> <p>14 you asked me. I think I am.</p> <p>15 Q. Do you consider yourself to be knowledgeable</p> <p>16 and trained and have experience with the design of</p> <p>17 clinical trials?</p> <p>18 A. Yes, sir, because I told you that we did</p> <p>19 several.</p> <p>20 Q. Have you ever done one on a testing of a</p> <p>21 medical device, not the -- the two that you talked to me</p> <p>22 about were actually not testing a medical device but</p> <p>23 testing the protocols about using a medical device in</p> <p>24 certain circumstances?</p> <p>25 A. That's correct.</p>
<p style="text-align: right;">Page 95</p> <p>1 A. I -- excuse me. I haven't seen the detailed</p> <p>2 comments on that, but in general, yes, sir, I understand</p> <p>3 that's true.</p> <p>4 Q. Would you agree with the statement that</p> <p>5 experience as a surgeon alone does not translate into</p> <p>6 experience with or knowledge of the appropriate testing</p> <p>7 a medical device manufacturer should undertake when</p> <p>8 preparing a device for the market?</p> <p>9 A. Is that something I said in my report?</p> <p>10 Q. No. I'm asking whether you agree with the</p> <p>11 concept.</p> <p>12 A. I'm sorry. Would you repeat that again?</p> <p>13 Q. Sure. Experience as a surgeon alone does not</p> <p>14 translate into experience with or knowledge about the</p> <p>15 appropriate testing a medical device manufacturer should</p> <p>16 undertake when preparing a device for the market?</p> <p>17 A. It may not encompass everything, but</p> <p>18 experience of the surgeon would certainly incorporate</p> <p>19 some of the things that would be appropriate to look</p> <p>20 for.</p> <p>21 Q. Do you feel that you have additional</p> <p>22 experience with product testing or clinical trials that</p> <p>23 sets you aside from an average pelvic surgeon related to</p> <p>24 the transvaginal mesh?</p> <p>25 A. I wouldn't normally say this about myself. I</p>	<p style="text-align: right;">Page 97</p> <p>1 MS. THOMPSON: Object to form.</p> <p>2 A. You're accurate about that. And then I</p> <p>3 referred to one other, which doesn't have any name on</p> <p>4 it, which was the animal model looking at Pelvicol. But</p> <p>5 have I done a study looking at a specific pelvic -- or a</p> <p>6 specific device in surgery from a clinical standpoint in</p> <p>7 humans, and the answer is no.</p> <p>8 Q. (BY MR. WEBB) Do you consider yourself an</p> <p>9 expert in the regulations or standards that govern IFUs?</p> <p>10 A. I'm not in a position to be involved in the</p> <p>11 regulations. I'm in a position as a user to know what</p> <p>12 would be reasonable for me to know about. So in that</p> <p>13 sense, I do feel I'm an expert on the receiver end. I'm</p> <p>14 not an expert on the development end.</p> <p>15 Q. Have you ever advised a company on how to</p> <p>16 design or word an IFU?</p> <p>17 A. No.</p> <p>18 Q. Are you familiar with the industry process</p> <p>19 governing IFUs?</p> <p>20 A. I do not know the process.</p> <p>21 Q. Have you ever performed a literature search</p> <p>22 relating to IFUs?</p> <p>23 A. You know, actually, I have read about IFUs.</p> <p>24 That was several years ago, and I don't have it in my</p> <p>25 report, but the truth is I have looked at that and</p>

25 (Pages 94 to 97)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 98</p> <p>1 looked at the fact that there are certain requirements,  2 but -- so I've read about it. I don't -- I haven't  3 participated in developing an IFU.  4 When I read the 510(k) application for  5 these products, part of the exchange with the agency and  6 the company was what to include in the IFU, and part of  7 the correspondence is -- which you have as documents  8 from Ethicon -- discussed whether or not the IFU ought  9 to be modified to include other information.  10 MR. WEBB: That's all I have.  11 MS. THOMPSON: I'll have a few questions,  12 but I'll just reserve them until the end of both  13 depositions, if we can agree that they apply to both.  14 MR. WEBB: That's fine with me.  15 MS. THOMPSON: All righty.  16 THE VIDEOGRAPHER: This concludes the  17 deposition of Dr. Shull. Going off the record, the time  18 is 12:00.  19 (Recess from 12:00 p.m. to 1:01 p.m.)  20 THE VIDEOGRAPHER: Back on the record.  21 This marks the beginning of Disc No. 3. The time is  22 1:01.  23 Q. (BY MR. WEBB) Dr. Shull, we took a break, and  24 this morning we were talking about Prolift and  25 Prolift+M, and you -- we went through your expert</p>	<p style="text-align: right;">Page 100</p> <p>1 entirely non-absorbable. The Prolift+M was different in  2 that a portion of the graft material is absorbable.  3 That's the primary difference.  4 To the best of my knowledge, the delivery  5 system itself was basically the same.  6 Q. (BY MR. WEBB) And we had some discussion this  7 morning when you were talking about absorbable material  8 when we were walking through the Prolift and Prolift+M.  9 Is that correct?  10 A. Yes.  11 (Exhibit No. 5 marked)  12 Q. (BY MR. WEBB) In your mind, is there any  13 substantial advantages or disadvantages to either a  14 Prolift or the Prolift+M?  15 A. I don't know that any advantages were  16 documented. The presumption was that by making a  17 portion of the Prolift absorbable by replacing the  18 nonabsorbable portion with Monocryl, that there would be  19 less mesh product left in the patient, and a variety of  20 problems could be minimized.  21 As I understand it, that was the  22 rationale for developing the Prolift+M. I don't know  23 that that's ever been proven to be the case.  24 Q. Have you seen any literature that would prove  25 it one way or the other?</p>
<p style="text-align: right;">Page 99</p> <p>1 report, your general report about those products. Is  2 that correct?  3 A. Yes. Yes, sir.  4 Q. Okay. And you have a separate expert report  5 that you have prepared for the Prosima product. Is that  6 correct?  7 A. Yes.  8 Q. And as we walk through, it appears, when I  9 compare your expert report for the Prolift and Prolift+M  10 to the Prosima expert report, there's a lot of it that's  11 very similar in some general details. Would that be a  12 fair statement?  13 A. Yes, sir.  14 Q. All right. And what I will do is I may just  15 ask you questions and say, "Would your answers be the  16 same about Prosima on these areas that are identical to  17 the Prolift and Prolift+M," and then you can either  18 agree with me or tell me how they differ. Is that a  19 fair way to approach it?  20 A. That's fine.  21 Q. All right. You have prepared -- and by the  22 way, is there any substantial difference in your mind  23 between the Prolift and the Prolift+M?  24 MS. THOMPSON: Object to form.  25 A. The Prolift -- the original product was</p>	<p style="text-align: right;">Page 101</p> <p>1 A. No, sir.  2 Q. I'm going to show you what we've marked as  3 Exhibit No. 5, which is basically your expert report on  4 Prosima. Do you have -- that's actually -- just giving  5 you back your Prolift one there.  6 A. I beg your pardon?  7 Q. And you have with you a copy of -- and what  8 I've done is just marked a copy I have of your expert  9 report.  10 A. This is the Prosima -- you have my updated  11 curriculum vitae, and here is the time sheet for working  12 on the Prosima report.  13 Q. Okay. The -- so Exhibit No. 5 is the Rule 26  14 expert report of Bob Shull regarding Prosima. Is that  15 correct, sir?  16 A. Yes, sir.  17 Q. Okay. And what you've given me is a time  18 sheet related to the time spent in reviewing documents,  19 researching, and preparing your report on Prosima.  20 Would that be a fair statement?  21 A. Yes. Yes, sir.  22 (Exhibit No. 6 marked)  23 Q. (BY MR. WEBB) The top page of Exhibit No. 6  24 looks like to be a check stub that was sent to you for  25 \$7,637.50, which matches an invoice dated February 7th,</p>

26 (Pages 98 to 101)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 102</p> <p>1 2016 that was sent to -- once again, you just have it  2 listed as Margaret on the invoice?  3 A. Yes. I sent it to her to distribute to the  4 appropriate individuals because she had the contact  5 addresses and whatnot.  6 Q. And that's Margaret Thompson. Right?  7 A. Yes, sir.  8 Q. Okay. You list review documents and  9 literature for 180 minutes. Finish review -- discussed  10 with Margaret and Breanne draft report, 365 minutes.  11 Revise and -- review and revise draft, 100. And final  12 report -- or phone call with Breanne and final report,  13 60, for a total of 705 minutes, or 11 hours and  14 45 minutes at \$650 an hour, which was \$7,637.50.  15 Is that correct, sir?  16 A. Yes, sir.  17 Q. Okay. Let me ask you generally: Were you  18 provided separate documents for the Prosima -- separate  19 Ethicon documents for the Prosima product?  20 A. Yes, sir. They're in this binder that I have.  21 These -- frankly, I can't remember why I have them out  22 separately, but I do. They relate to the Prosima, and I  23 don't believe I took them out of here -- and they may be  24 duplicated in here, but I have everything that I used in  25 this binder and in the -- or in the back of the front</p>	<p style="text-align: right;">Page 104</p> <p>1 "Anatomical study of prolapse surgery  2 with nonanchored mesh and a vaginal support device," the  3 "American Journal of Obstetrics and Gynecology," 2010.  4 "Case report: Internal pudendal artery  5 injury during prolapse surgery using nonanchored mesh,"  6 the "Journal of Minimally Invasive Gynecology," and  7 accepted for publication June 23rd, 2011.  8 Are these the articles that specifically  9 relate to Prosima that you -- Prosima that you relied  10 upon in preparing your report, Dr. Shull?  11 A. Yes, sir.  12 Q. Why did you understand that it was potentially  13 desirable to have a vaginal support device when you're  14 doing a surgical procedure for pelvic organ prolapse?  15 A. The way I understand the evolution of this  16 type of surgical procedure is that the authors hoped to  17 avoid the use of trocar placement for the arms or the  18 straps of the Gynemesh.  19 They understood that if the arms weren't  20 fixed either by trocars penetrating tissue spaces or by  21 stitching them in place, that there would need to be an  22 alternate way to keep the mesh approximated to the  23 anatomic spots where they were placed at the time of the  24 surgery.  25 I don't recall if the authors had tried</p>
<p style="text-align: right;">Page 103</p> <p>1 page.  2 MR. WEBB: Margaret, does the thumb drive  3 that you gave me earlier, does it cover this also?  4 MS. THOMPSON: It has both Prolift and  5 Prosima documents, yeah.  6 MR. WEBB: All right.  7 Q. (BY MR. WEBB) In the Prosima binder that you  8 gave me, there is a series of articles at the front, and  9 I'll just read them into the record. There's only five,  10 I think.  11 The first one is "Vaginal surgery for  12 pelvic organ prolapse using mesh and a vaginal support  13 device," published in the "BJOG: An Interventional  14 Journal of Obstetrics &amp; Gynecology," and it's dated  15 2008 -- accepted October 23rd, 2007.  16 Then there's the -- an article,  17 urogynecology, "One year clinical outcomes after  18 prolapse surgery with nonanchored mesh and vaginal  19 support device," the "American Journal of Obstetrics and  20 Gynecology," December 2010.  21 "Medium-term clinical outcomes following  22 surgical repair for vaginal prolapse with tension-free  23 mesh and vaginal support device." It looks to be the  24 "International Urogynecological Journal," published  25 online December 6th, 2011.</p>	<p style="text-align: right;">Page 105</p> <p>1 using glue of some sort to hold the straps in place.  2 It's possible they did, but I don't remember that.  3 The mechanism they chose to use was to  4 place the mesh straps into defined spaces, and then for  5 a time period in the recovery, use an object -- excuse  6 me -- which could fill the vaginal canal and minimize  7 the likelihood that the mesh arms or the mesh central  8 portion would either move or be displaced, and that  9 while the vaginal support device was in place, wound  10 healing would begin and perhaps keep the tissue in its  11 desired location.  12 Q. When was this product placed on the market?  13 A. I believe the product was actually sold  14 beginning in 2009.  15 Q. And when was it withdrawn from the market?  16 A. I believe that it was no longer available for  17 sale sometime in 2012.  18 Q. What is your understanding about the success  19 rate of this product?  20 MS. THOMPSON: Object to form.  21 A. In my review of the literature, the primary  22 physicians who developed the concept of vaginal support  23 device and the nonanchored mesh were Dr. Marcus Carey  24 and Dr. Mark Slack.  25 And Dr. Carey published an article -- or</p>

27 (Pages 102 to 105)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 106</p> <p>1 he began to recruit patients into a study that compared  2 patients who had the nonanchored mesh to patients who  3 had traditional surgery so he could have a baseline to  4 determine what kind of success is obtained with standard  5 surgery. Then he hoped to be able to improve on the  6 anatomical outcomes using the vaginal support device.  7 And as he developed this product, he did  8 a study, in fact -- and that's involved in the articles  9 I have -- as the first step toward justification for  10 advancing on to a study using the device which  11 ultimately became Prosima.  12 Q. (BY MR. WEBB) And is the study you're talking  13 about the one that's entitled "Vaginal surgery for  14 pelvic organ prolapse using mesh and a vaginal support  15 device"?  16 A. This is not the first study. Actually, the  17 first group of patients recruited -- I believe that  18 article was reported in 2009, actually. It may be the  19 first one in the binder which I gave you there.  20 This is a subsequent group of patients  21 that -- for whom Dr. Carey, who is from the United  22 Kingdom, was the primary author. Dr. Slack was the  23 primary author on the patients who were recruited  24 initially for the comparison of --  25 Q. Does that look like it's the same article to</p>	<p style="text-align: right;">Page 108</p> <p>1 these. I thought that they may be different, but  2 they're not.  3 Q. And were these articles in the information in  4 the binder that was provided to you by plaintiffs'  5 counsel?  6 A. Yes, they were.  7 Q. The five articles that I read the names into  8 the record, were those provided by plaintiffs' counsel,  9 or was that something you found in your own independent  10 research?  11 A. They were provided by counsel.  12 Q. Okay. It appears there's also some internal  13 Ethicon documents?  14 A. Yes, sir, there are.  15 Q. And some product literature related to  16 Prosima?  17 A. Yes, that's correct.  18 Q. Does it appear that Dr. Carey's research was  19 an attempt to address some of the issues that you had  20 reported or that you had opined about this morning  21 regarding the use of trocars when using the Prolift and  22 the Prolift+M products?  23 A. Yes, sir. Excuse me. And the other thing he  24 did is before doing that, he reported -- and that's the  25 article that is actually in the British Journal of</p>
<p style="text-align: right;">Page 107</p> <p>1 you?  2 A. Let me just look at the next one.  3 Yes, sir, it is the same one. I'm sorry.  4 I'm sorry. It is the same one. But there's another one  5 which was published a little later. I just have to find  6 it. Maybe I have it in here.  7 Well, actually, there's another one I  8 recall, which I referenced in my report, but I can't  9 find it right here, as a matter of fact. May I see my  10 general report just a moment?  11 Okay. I do have the other article. It's  12 the one-year clinical outcomes. I beg your pardon. I  13 have that.  14 Ask me the question again, would you,  15 please? I started looking, and I forgot exactly what  16 you asked me.  17 Q. I think the question was whether or not the  18 article that I handed you was the same as --  19 A. Yes, sir.  20 Q. -- the article that's the first article in  21 your binder?  22 A. Yes, sir, it is. And I think what I must have  23 done, I must have copied these articles and just taken  24 them out separately, because this binder has other  25 information, and I wanted to be able to just work with</p>	<p style="text-align: right;">Page 109</p> <p>1 Obstetrics &amp; Gynecology in 2009. Dr. Carey took a group  2 of patients that he himself recruited and operated on  3 doing mesh with standard surgery so he would have a  4 baseline to know in his own experience what the  5 anatomical outcomes were using mesh alone or using no  6 mesh.  7 He did that first, and then he worked on  8 the vaginal support device in an effort, as you pointed  9 out, to see if not using trocars would minimize or  10 eliminate some of the initial complications with using a  11 mesh product.  12 Q. Do you have a complaint -- looking through  13 your report, it's not clear to me. Do you have a  14 complaint about the vaginal support device itself, or  15 are your complaints related to the use of mesh in the  16 type of surgery that the Prosima is used in separate and  17 apart from the vaginal support device?  18 A. Well, the vaginal support device had as its  19 predicate a device called Silimed, which was cleared to  20 use in women having radiation therapy on the pelvis or  21 having pelvic -- creation of a new vagina. The Silimed  22 was used to try to maintain the caliber of the vaginal  23 canal.  24 In this particular use of it, there's a  25 different indication for the use because these women</p>

28 (Pages 106 to 109)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 110</p> <p>1 were having reconstructive surgery using a synthetic 2 product. The Silimed hadn't been used for that 3 previously. The thing that it did do, it avoided the 4 passage of trocars. 5 So does the Silimed in and of itself have 6 any potential adverse effect? We don't know that 7 because, to the best of my knowledge, there was not a 8 group of women who had surgery without a product who had 9 the support device only. So we don't have any 10 information to say the vaginal support device is likely 11 to be associated with any specific problems. It's just 12 the predicate was used for a different reason. 13 Q. Well, and, in fact, one of the documents you 14 were provided was the FDA Department of Health and Human 15 Services approval letter dated August 5th of 1998 in 16 which Silimed, LLC was approved under 510(k) as a 17 Class II device, and it was determined it was 18 substantially equivalent to the devices marketed in 19 interstate commerce prior to May 28, 1976, the enactment 20 date of the medical device amendments, and, therefore, 21 it was subject to the general controls provision of the 22 food -- federal food, drug, and cosmetic act. 23 So there were requirements for annual 24 registration, listing of devices, good manufacturing 25 practice, labeling, and prohibitions against misbranding</p>	<p style="text-align: right;">Page 112</p> <p>1 That is the exact same wording except you 2 have replaced Prolift and Prolift+M devices with the 3 Prosima devices. Is that correct? 4 A. Yes, sir. 5 Q. And would your -- are we talking about 6 separate timeframes here for when the Prolift and the 7 Prolift+M devices came on the market compared to the 8 Prosima? 9 A. They're -- excuse me. They're different 10 timeframes. Excuse me. Gynemesh received 510(k) 11 clearance before either of these, and then in the 12 timeline, the next product that was developed was the 13 Prolift without the M. It was Prolift. 14 So Prolift was developed, and then 15 subsequent to that, the Prolift+M was a modification, 16 and subject to that modification was the Prosima. And 17 they were all separated by at least a year or more in 18 between. So the Prosima was the last in that sequence 19 of events. 20 Q. All right. Did the Prolift, the Prolift+M, 21 and the Prosima all use the same Gynemesh? 22 A. They did -- with the exception of the 23 Prolift+M, had a portion of the mesh that was 24 absorbable. And the shorter name for the absorbable 25 part is Monocryl, M-O-N-O-C-R-Y-L. There's a chemical</p>
<p style="text-align: right;">Page 111</p> <p>1 and adulteration. 2 So do you have any complaints as we -- 3 I'm trying to parse this to see what we have to discuss. 4 Do you have any complaints about the Prosima or 5 Prosima -- the vaginal support device portion of the 6 Prosima device? 7 MS. THOMPSON: Object to form. 8 A. I have -- excuse me. I have no knowledge that 9 the device in and of itself created a problem, because 10 we don't have any information that the device was used 11 without mesh. So I'm not -- I don't believe I'm opining 12 about the support device as a standalone issue. It's 13 simply used in association with a mesh product. 14 Q. (BY MR. WEBB) Did you see any reports of any 15 adverse events or adverse reactions when it's used in 16 conjunction with the mesh but that could be attributed 17 directly to only the vaginal support device? 18 A. No, sir. 19 Q. I'm going to try to compare the opinions you 20 have Prosima against the opinions you expressed in 21 regard to Prolift and Prolift+M. 22 Your No. 1 opinion, "At the time of this 23 introduction, there was insufficient scientific evidence 24 supporting the implantation of the Prosima devices for 25 pelvic organ prolapse."</p>	<p style="text-align: right;">Page 113</p> <p>1 name, which is longer. 2 But the Prolift+M had the Monocryl, and 3 that dissolved after a period of several months, and you 4 were left with a smaller amount of the Gynemesh 5 permanently implanted in someone. 6 Q. Did you see any -- let's compare the three. 7 The complaints you had about the Prolift, did the 8 Prolift+M relieve any of those complaints? 9 A. We don't have any information to indicate that 10 that's true because the thing that's considerably 11 different about the Prolift and Prolift+M is that 12 they're both trocar based, and the product -- the arms 13 that go with the Prolift and Prolift+M are still 14 anchored in muscle. 15 The main difference with the Prosima is 16 instead of arms, they have what are referred to as 17 straps, and the straps are actually put into place, but 18 the device that puts them in place does not penetrate 19 the same muscle group in the pelvis. So it's a 20 non-trocar based system using the same mesh. It just is 21 placed in a different way, and it just doesn't end up 22 with the mesh arms -- excuse me -- going through muscle 23 spaces. 24 Q. Did you actually -- have you seen any 25 comparison in the reported complications between the</p>

29 (Pages 110 to 113)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 114</p> <p>1 Prolift, the Prolift+M, and the Prosima? I mean, is  2 there any difference in the complication rates? Are  3 there different complications associated with the  4 products?  5 A. I think the general categories are similar.  6 The idea behind the use of the Prosima is to eliminate  7 the trocar use, and let's presume that part of the  8 pelvic pain complaints are related to the mesh arms on  9 the Prolift and Prolift+M going through a series of  10 tissues, including muscle, and being left there and  11 being exposed to vessels and nerves. And if that  12 product then changes configuration, it may cause pain  13 where the muscle has been penetrated, and it becomes  14 very difficult to remove.  15 So as I understand it, the concept was to  16 eliminate that portion of the procedure and simply lay  17 the product against a structure in the pelvis and not  18 penetrate a structure, because the Prolift and Prolift+M  19 actually penetrated muscles and nerves in the pelvis.  20 And theoretically, there should not be  21 the same type of complaints in terms of the mesh arms,  22 but it doesn't eliminate or perhaps even reduce a  23 likelihood of mesh exposure or mesh being approximated  24 to structures and getting smaller and then pulling on  25 structures that are innervated and resulting in pain or</p>	<p style="text-align: right;">Page 116</p> <p>1 product for a variety of things in the body -- it could  2 be the eye, it could be the heart, it could be the  3 pelvis -- that is totally inert and doesn't stimulate  4 any excess reaction in terms of inflammation or scarring  5 or anything else. That would be the ideal impact that  6 almost never happens anywhere.  7 Q. (BY MR. WEBB) Well, in fact, it does not  8 happen. There is no material that's completely inert.  9 Correct?  10 MS. THOMPSON: Object to form.  11 A. Once it's implanted in the body, you would  12 think it -- stainless steel, for example, you would  13 think would be inert, but the truth is there still is a  14 response because surgery, in and of itself, requires  15 incisions and repair, and when the incisions heal,  16 there's a cascade of events that occur, including, at  17 least temporarily, inflammation.  18 Q. (BY MR. WEBB) Your second opinion about the  19 Prosima device is the exact same opinion that you had  20 about Prolift and Prolift+M, that they do not represent  21 a significant departure -- they do represent a  22 significant departure from traditional surgical  23 procedures performed by -- for pelvic organ prolapse,  24 and that they offer no advantage over a traditional  25 repair. Would you agree with that?</p>
<p style="text-align: right;">Page 115</p> <p>1 in distortion of the vaginal canal. So those things  2 still could happen.  3 Q. Did you do a comparison of the reported  4 complication rates for each of these products compared  5 to the others?  6 A. Not side by side.  7 Q. Off the top of your head, is there one that  8 has less complications than the other, or do they all  9 kind of fall into the same category as far as --  10 A. They are generally -- they're generally the  11 same in the sense that both of -- both the Prosima and  12 the Prolift and Prolift+M are both associated with mesh  13 exposures. Both are associated with the surface area,  14 the mesh, becoming smaller and causing contraction or  15 scarification and banding, which can be associated with  16 pain and alteration of the vaginal canal size. So those  17 things are similar.  18 Q. Would you agree with the statement that any  19 foreign body that's introduced in the body is going to  20 cause some reaction, whether it's inflammation or  21 scarring or collagen deposition or contracture?  22 MS. THOMPSON: Object to form.  23 A. By and large, all foreign bodies are going to  24 create some type of response.  25 Under ideal circumstances, we could use a</p>	<p style="text-align: right;">Page 117</p> <p>1 A. Yes, sir.  2 Q. And we already talked about the -- what you  3 consider traditional surgical procedures, and those  4 would have been procedures that had been performed prior  5 to 2000?  6 A. By and large, that would be correct. Some in  7 2000 -- or beg your pardon, 1996. Dr. Julian had  8 reported on his use with Marlex, which is a synthetic  9 wrap. So because his report was in 1996, obviously he  10 began recruiting patients earlier than that, but he  11 first reported it in 1996, but that was the exception.  12 Not very many people were doing that.  13 Q. Do you consider that to be traditional  14 surgical procedure or --  15 A. Without the use of mesh products, yes, sir.  16 Q. Was that product -- or is that product still  17 on the market today?  18 MS. THOMPSON: Object to form.  19 A. Well, the Marlex, which Dr. Julian used, may  20 be on the market. I actually don't know that. I don't  21 believe that anyone uses it in any gynecological  22 surgery, but could it be used for something else? It's  23 possible. I wouldn't know that.  24 Q. (BY MR. WEBB) That was the sheep material.  25 Correct?</p>

30 (Pages 114 to 117)



Bobby Lewis Shull, M.D.

Page 118	Page 120
<p>1 A. Marlex is another synthetic sling. So it's</p> <p>2 not a biomaterial. There are biomaterials -- when I</p> <p>3 talked about Pelvicol earlier, Pelvicol is a</p> <p>4 biomaterial, and that morphed into several different</p> <p>5 things by a different company, but those came from</p> <p>6 animals. They're basically what's called a xenograft.</p> <p>7 Marlex was one of the early synthetic fibers that was</p> <p>8 made, and I don't know that anybody uses that in</p> <p>9 medicine anymore.</p> <p>10 Q. No. 3, "The vagina is a different environment</p> <p>11 from the abdominal wall. Maintenance of vaginal</p> <p>12 compliance and distensibility is essential for bowel,</p> <p>13 bladder, and sexual function."</p> <p>14 That's the same opinion that you</p> <p>15 expressed relating to the Prolift and Prolift+M.</p> <p>16 Correct?</p> <p>17 A. Yes, sir, and that's because, again, the</p> <p>18 vaginal canal cannot be sterilized. That's one of the</p> <p>19 key differences. Plus, there were other qualities about</p> <p>20 the vaginal tissue that were important.</p> <p>21 Q. And you discussed those earlier today, didn't</p> <p>22 you?</p> <p>23 A. Yes, sir. Flexibility, distensibility, and</p> <p>24 sensitivity, and -- all those things. Excuse me.</p> <p>25 Q. No. 4, "Insertion of the device containing</p>	<p>1 discussed earlier, foreign bodies invoke an inflammatory</p> <p>2 response. So even though there isn't a trocar, the</p> <p>3 local inflammatory response still occurs, and in these</p> <p>4 spaces which are developed, there still are vessels and</p> <p>5 nerves, and it's entirely possible that the mesh straps</p> <p>6 could form scar -- scar tissue in these pockets.</p> <p>7 And if the mesh then shrinks, the mesh is</p> <p>8 going to pull on this area that's innervated,</p> <p>9 vascularized, whatnot. It may be a little different</p> <p>10 than going all the way through the muscle, but it</p> <p>11 doesn't avoid that all together.</p> <p>12 Q. Have you, in your clinical practice, ever seen</p> <p>13 a patient that had Prosima?</p> <p>14 A. Yes, sir. I've done an explant surgery, and</p> <p>15 when I gave you my earlier times that I acted either as</p> <p>16 a treating physician or an expert or a general report,</p> <p>17 the patient in whom the -- I was asked to be deposed as</p> <p>18 a treating physician of someone who had been treated</p> <p>19 with Prosima.</p> <p>20 Q. That was Rabiola?</p> <p>21 A. Yes, sir.</p> <p>22 Q. Okay. And is that the one time that you've</p> <p>23 seen a patient with Prosima?</p> <p>24 A. Well --</p> <p>25 MS. THOMPSON: Object to form.</p>
Page 119	Page 121
<p>1 polypropylene mesh straps presents specific risk and is</p> <p>2 inconsistent with sound pelvic reconstructive surgical</p> <p>3 procedures."</p> <p>4 That's different than the opinion that</p> <p>5 you had related to Prolift and Prolift+M.</p> <p>6 "Insertion of a mesh device containing</p> <p>7 arms involving the blind passage of trocars presents</p> <p>8 specific risks and is inconsistent."</p> <p>9 So Prolift and Prolift+M, you had the</p> <p>10 insertion of a medical device with -- by using trocars.</p> <p>11 You don't use trocars with the Prosima. Right?</p> <p>12 A. Yes, sir, that's correct.</p> <p>13 Q. And tell me what specific risks are associated</p> <p>14 with using a polypropylene mesh with straps rather than</p> <p>15 the ones with arms and the trocars.</p> <p>16 A. I think there are several possibilities.</p> <p>17 Excuse me. One is in the dissection, getting into the</p> <p>18 proper space in the pelvis to place the straps, and that</p> <p>19 requires a sophisticated level of knowledge of anatomy</p> <p>20 and dissection. So getting to the desirable spaces to</p> <p>21 place the graft is one thing.</p> <p>22 The second thing is once these spaces are</p> <p>23 dissected and the material is placed into the spaces and</p> <p>24 wound healing begins, access to those spaces is not as</p> <p>25 easy as it was the first time, and we know, as we</p>	<p>1 A. I know that for certain. There could be</p> <p>2 others.</p> <p>3 What happens from a practical standpoint</p> <p>4 is we don't always have the opportunity to note, and the</p> <p>5 patients may or may not recall exactly what was done,</p> <p>6 and they may remember that something sounds like it</p> <p>7 began with a certain letter.</p> <p>8 So let's say Prosima and Prolift start</p> <p>9 with the same letter, or something that sounds like it,</p> <p>10 Apogee or -- so patients get confused about that, and we</p> <p>11 actually don't know exactly what happened.</p> <p>12 And you would say, "Well, couldn't you</p> <p>13 ask them about did they have puncture sites externally,"</p> <p>14 which would help you decide that. And I do ask them</p> <p>15 that. And there are people who don't remember if they</p> <p>16 had a puncture site somewhere or not. They just don't</p> <p>17 remember that.</p> <p>18 So I didn't have the operative note on a</p> <p>19 lot of these people. I know I had the one patient,</p> <p>20 Mrs. Rabiola, and I may have had others. It's just I</p> <p>21 can't tell you for sure how many.</p> <p>22 Q. (BY MR. WEBB) And refresh my memory if I</p> <p>23 already asked you this, but did you -- you've identified</p> <p>24 at least some patients who had Prolift. Do you know of</p> <p>25 any that had Prolift+M?</p>

31 (Pages 118 to 121)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 122</p> <p>1 A. No, sir, I don't know that. That was a later 2 iteration of the product, and I would say without the 3 operative note, practically no patient would remember 4 that. If they remember Prolift, that would be great -- 5 or the name of anything else, as far as that goes, not 6 just Prolift. 7 Q. Did you see any medical literature that talked 8 about the adverse events or the problems associated with 9 the Prosima or Prosima product? 10 A. Yes, sir, two things. The one-year clinical 11 follow-up -- or outcomes after prolapse surgery, which 12 was published in 2010 in the American Journal of 13 Obstetrics and Gynecology, Dr. Halina Zyczynski. So 14 they looked primarily at vaginal support, so that's one. 15 Their primary goal was not to look at other things, but, 16 in fact, they did record other things about pain with 17 balloon removal and pain after surgery. So they did 18 look at other factors. 19 And in their discussion -- these are the 20 authors themselves discussing their own manuscript, 21 which most authors do, by the way. Most authors will 22 look at their -- the strengths and weaknesses of their 23 manuscript. That's one of the expectations that you 24 would do. 25 And these authors said that the absence</p>	<p style="text-align: right;">Page 124</p> <p>1 pointed out is with these -- with this procedure they're 2 specifically referring to, there's a learning curve, 3 and, in fact, that happens with all surgery. There's a 4 learning curve that goes along with it. 5 And again, they comment on their own 6 study saying that their major concern is they don't have 7 a control group who was operated on without using either 8 the support device or the mesh. 9 So all the authors recognize that, and 10 the truth is what they're primarily looking at is a 11 group of women who have the -- this case, the Prosima, 12 which is the mesh and the support device, and they're 13 looking primarily at do they get better anatomical 14 outcomes. 15 And when you and I talked this morning, 16 one of the stimuli for wanting to find something helpful 17 is to reduce the likelihood that a woman will have 18 surgery for poor support and not have the best 19 opportunity to get that poor support corrected. So all 20 of them want to improve the anatomical outcomes. That's 21 the goal of all of these things. 22 Q. And does it appear that they did have more 23 success with the anatomical results? 24 A. Yes. It depends again on how strictly someone 25 defines "success." They had really rigid criteria for</p>
<p style="text-align: right;">Page 123</p> <p>1 of a comparator group -- which means someone had a 2 similar surgery, same group of people -- they didn't 3 have one of those, so it's hard to know how the outcomes 4 in terms of pain and other issues compare to what they 5 would normally do without mesh. 6 But they didn't have -- another outcome 7 that was reported by Dr. Sayer, S-A-Y-E-R, as the 8 primary physician, and included Dr. Slack, who was one 9 of the earlier users, all a part of what's called a 10 Prosima study group, and they looked at outcomes of 11 surgery. And it was designed to evaluate women who had 12 to have at least two years of follow-up. 13 And that's what they wanted to report on. 14 They describe the type of people they operated on, the 15 product that they used, and then looking at anatomical 16 outcomes, that was their primary outcome measure, which 17 is what most authors have had, quite frankly. 18 Then they looked at mesh exposures and 19 need to be reoperated for recurrent prolapse. So that 20 was at a minimum of two years after surgery, and these 21 authors referred to that as medium term -- we had spoken 22 earlier about long-term outcomes. So two years or more 23 is actually much better than six months or 12 months. 24 It's still referred to as medium term. 25 And the other thing I think the authors</p>	<p style="text-align: right;">Page 125</p> <p>1 anatomical outcomes. The success rate isn't as high as 2 if they use a more clinically applicable outcome. 3 And in general -- this applies to these 4 authors, and in general to most authors. What they find 5 is that if you use anatomy in what's called the treated 6 compartments -- so if it's by the bladder or the rectum 7 and you treat those -- use anatomy in the treated 8 department, as a generalization, the anatomical outcomes 9 are equal to or better than not using mesh. So that's 10 one outcome variable. 11 What has become apparent in these 12 different products that have been used, two things. One 13 is the untreated compartment. So let's say there are 14 two or three places in the pelvis that could require 15 surgery, but today the woman really needs surgery in one 16 compartment. 17 What we are learning is that that one 18 compartment is treated with a mesh product, that the 19 longer you follow her, the more likely the untreated 20 area may prolapse out, or something adjacent to where 21 the product is may prolapse. So that was sort of -- 22 that was not necessarily anticipated. So that's one 23 thing. 24 And the other thing that they are looking 25 for is not just anatomical success. It's how many</p>

32 (Pages 122 to 125)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 126</p> <p>1 people have erosion, bleeding, with a mesh product.  2 So when they report outcomes, in general,  3 authors are going to say that if you use anatomy as the  4 endpoint, that mesh products in the anterior compartment  5 specifically have a better anatomical outcome than  6 non-mesh. The follow-up -- the extension of that is the  7 quality of life in patient subjective satisfaction is  8 generally equal in mesh and non-mesh product surgeries.  9 The third area they look at is  10 requirement for reoperation for any reason. And almost  11 universally what all authors find is the need for repeat  12 surgery is greater in the women who have mesh than the  13 women who don't.  14 And the indication for repeat surgery  15 could be recurrence of the prolapse. It could be pain.  16 It could be exposure of the mesh. But in the aggregate,  17 women who have mesh end up having more likelihood to  18 have surgery than someone who didn't.  19 So then what some people look at is they  20 say, well, since the anatomy is better, how do we  21 quantify what we would have to do in order to say that  22 it's really a good idea to use the mesh product?  23 And if you said you used mesh products on  24 everyone, for example, what you would find is that for  25 prolapse, for example, you would have to put mesh in</p>	<p style="text-align: right;">Page 128</p> <p>1 Q. Item 5, "There were no studies prior to the  2 introduction of the Prosima device demonstrating safety  3 and efficacy of the vaginal support device - balloon  4 assembly."  5 Do you know what kind of studies were  6 performed on the Silimed vaginal stent?  7 A. Not by itself. I'm not sure -- excuse me. I  8 don't know if there were any efficacy studies on  9 Silimed, quite frankly, because it was indicated for  10 such a defined group of women that it would be -- it's  11 possible, but I'm not aware of it, that someone would be  12 able to look at a group of women who were treated with  13 and without the Silimed device. I don't know that, and  14 I don't ever remember hearing that discussed anywhere.  15 Q. Your Item 6 is the same opinion, "Traditional  16 surgical repairs are effective. The medical literature  17 does not show improved outcomes with the use of the  18 Prosima device or any other transvaginally placed mesh."  19 That's the same opinion you had with  20 Prolift and Prolift+M?  21 A. Yes, sir. Dr. Carey himself actually showed  22 that.  23 Q. Well, you say it does not show improved  24 outcome. Does it show comparable outcomes?  25 A. I think in the aggregate, if you look at the</p>
<p style="text-align: right;">Page 127</p> <p>1 anywhere between six and 19 additional people from what  2 you're currently doing, six to 19, to reduce the  3 likelihood that one person would have more surgery. In  4 other words, one out of six would be 15 percent. One  5 out of 19 would be 5 percent. So you'd have to treat a  6 lot of extra people with mesh to minimize the likelihood  7 that if they didn't have it, that they would get  8 recurrent surgery.  9 So I don't think anybody -- this is my  10 assessment of it. You asked me earlier, I think, about  11 if I look at the literature. I don't believe that  12 anyone is disputing that in the anterior compartment of  13 a vagina, mesh can offer a better anatomical support.  14 In the posterior compartment, in the top  15 of the vaginal canal, that is probably not true. It is  16 probably not better than. So with the anterior  17 compartment, the anatomical outcomes may be better.  18 What we also know is exposure occurs in  19 the anterior compartment, or the posterior, either one.  20 So we know there's mesh exposure, and we know that for  21 almost all authors, the reoperation rate is greater when  22 you use mesh, global reoperation rate.  23 So for some women, there are benefits.  24 Other women, the cost of having it is greater than the  25 benefit.</p>	<p style="text-align: right;">Page 129</p> <p>1 anatomy, they're probably very comparable. If you look  2 at reoperation rate, which I mentioned before, they're  3 not comparable, because in any women who has mesh placed  4 in the vagina, there is an almost irreversibly low  5 likelihood that she will get mesh erosion and require  6 either medical treatment or excision of the mesh.  7 So in that sense, the anatomy could be  8 similar, but the reoperation rate is going to be higher,  9 and that's been reported by all authors in women who  10 have mesh. Excuse me.  11 Q. What about other complaints like dyspareunia?  12 A. The other complaints are not easy to  13 determine, and there are reasons for that. For one  14 thing, unless the author has set up a prospective study  15 looking for a lot of variables, women who have any kind  16 of surgery, with or without mesh -- so if you ask them  17 about their pain complaints after surgery, pain with  18 intercourse, pain with surgery, pain with anything, it  19 doesn't really make any difference -- if you didn't have  20 a baseline for that same variable and have an answer for  21 it before the operation, then what happens is called  22 recall bias.  23 So if someone were to ask me what  24 happened three months ago, I may or may not remember  25 that. If they ask me a year ago, I'm less likely to</p>

33 (Pages 126 to 129)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 130</p> <p>1 remember. So all that information needs to be collected 2 prospectively, and, in fact, it generally isn't. 3 There are one or two articles that were 4 in that previous report on Prolift from Dr. Anne Weber, 5 who was at the Cleveland Clinic, who tried to look 6 prospectively at the specific sexual complaints before 7 and after surgery, but it wasn't in the context of using 8 mesh. 9 I think all of us agree that women can 10 have pain following surgery. The issue is, partly, how 11 can you manage that pain and what seems to be associated 12 with it in the absence of a mesh product. You're 13 dealing with a certain set of issues. It could be a 14 trigger point. It could be a scar is tender. It could 15 be a variety of things. 16 Once the mesh is introduced, the mesh 17 itself may be associated with the pain instead of a 18 local inflammatory reaction. So it wouldn't necessarily 19 be that a woman would have no pain if they didn't have 20 mesh. I don't think anybody says that. It would be 21 they have a different kind of pain, and the management 22 of it is potentially much more problematic. 23 Q. List for me what severe life-changing 24 complications that are not seen with traditional pelvic 25 reconstructive surgery that you find with mesh, unless</p>	<p style="text-align: right;">Page 132</p> <p>1 term they use is their life has been spoiled by pain, 2 and that's what the patients describe. They can't do 3 their normal activities. And once that happens, there's 4 a whole cascade of events that affect their 5 relationships with their sexual partners, their family, 6 their job, their everything. 7 So there are those people that have this 8 downward cascade. There are those that reset to a lower 9 baseline. And this isn't the same thing, so I'm not 10 purporting that it is. But my personal observation of 11 that in my own family -- not with mesh, but I'll tell 12 you who how people reset a baseline. My wife who died 13 had rheumatoid arthritis, and in order to function 14 normally, she had to reset a baseline of how to work. 15 Because you can't expect to do everything you did 16 before. You're going to be disappointed. You have to 17 reset what you're capable of doing. 18 And in this case, that's what some of the 19 women with mesh have done. They've reset their baseline 20 at a lower level than before. 21 That's when I say life altering. That's 22 what I mean by that. 23 Q. Give me an approximation of the sizes of these 24 groups, these three groups you're talking about. 25 A. In this group that was reported from the</p>
<p style="text-align: right;">Page 131</p> <p>1 you've already gone through them. 2 A. No, sir. I haven't answered that for you. In 3 the referenced articles, which are in my Prolift report, 4 there are two reports from the University of Utah, and 5 Dr. Ingrid Nygaard is one of the authors on both of 6 those reports in our professional journals, and one of 7 them provide free text, so women are allowed to describe 8 what's happened to their lives when they develop these 9 complaints. 10 So the life-altering ones that are in one 11 of her articles says that women who acquire these 12 complaints fall into three categories. One category is 13 they acquire pain, they see someone, they're managed, 14 and for all practical purposes, they don't have 15 significant complaints after that. 16 There's another group of women who 17 acquire pain complaints, and they're treated, and their 18 complaints don't go away, but they acquire a new sort of 19 baseline activity in their lives that is reduced -- 20 their quality of life is reduced from before, but it's 21 more or less stable. 22 And there's a third group of women in 23 whom they acquire pain complaints and they have an 24 intervention, and they are caught in what this group has 25 called a downward spiral of their health, or the other</p>	<p style="text-align: right;">Page 133</p> <p>1 University of Utah, I want to say that the ones who 2 responded and felt better and the ones who reset their 3 baseline were more or less equal. So I'm going to make 4 these percentages up, because I don't remember the exact 5 percentage, but it's close to accurate -- that about 6 40 percent fell into each of those, and there's in the 7 neighborhood of 20 percent who have this continuing 8 spiral of they hurt, they feel bad, it affects their 9 job, their relationship, and all those things. 10 Q. Okay. 11 A. That's a selective group of people who have 12 come specifically because they have had complication of 13 their prior surgery. I'm not suggesting that 40 percent 14 of all women who have the products have pain and get 15 better and 40 percent reset and 10 percent are on a 16 downward spiral. I'm referring to the group of people 17 who were bothered enough to come to the doctor to seek 18 intervention because of their pain complaints. 19 Q. Any other life-changing complications that you 20 have not described earlier? 21 A. Well, the -- one of the things I would 22 consider to be life changing is the requirement for 23 multiple interventions, and the interventions could be 24 physical therapy, for example. 25 Well, how does that change your life?</p>

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 134</p> <p>1 Well, it means -- depending on what you're capable of  2 doing, you have to get transportation to and from  3 wherever you're going and spend a certain amount of time  4 there. So there's a time commitment to that over an  5 extended time period. That's at one level.  6 Another level is the multiple surgeries,  7 and the multiple surgeries involve everything that could  8 go the matter with surgery, including anesthesia, the  9 recovery, the expense, the time lost for wages, however  10 you calculate all those things. But if you have one  11 surgical intervention, there's a certain level of time  12 away and cost associated with it, but if you have -- in  13 the case as of some of these people, multiple -- when I  14 say "multiple," I mean more than two -- where they have  15 multiple times where they are having to have surgery and  16 miss work and recovery and whatnot. That's life  17 altering.  18 The other one which affects people in  19 general is their relationship with their spouse or their  20 partner, so -- all those things happen that really --  21 they change the dynamic in someone's life.  22 Q. Well, it sounds to me like what you've just  23 described is going to be case specific to each patient.  24 MS. THOMPSON: Object to form.  25 A. Well, I think part of the point is what you've</p>	<p style="text-align: right;">Page 136</p> <p>1 From a technical standpoint, that would  2 be on a scale that's more difficult than someone who has  3 a product lying against a surface area. There still is  4 the difficulty of the dissection to identify the  5 product, but when it's adjacent to something and you  6 don't have to go into the structure to get it out, the  7 degree of technical difficulty in general should be  8 less.  9 Q. Okay. Characteristics of polypropylene mesh  10 when implanted vaginally for pelvic organ prolapse  11 include chronic inflammation.  12 Was chronic inflammation warned about in  13 the product warnings?  14 A. You know, I don't remember if the specific  15 term "inflammation" was used or not. I know that it  16 says the mesh can erode, they can have pain or  17 infection. I'm not -- I don't remember clearly if it  18 says "inflammation." I don't know that.  19 Q. How about foreign body reaction, or do you  20 think it's even necessary to warn about foreign body  21 reaction?  22 MS. THOMPSON: Object to form.  23 A. Well, you asked earlier, well, am I an expert  24 on product information and whatnot. I am not an expert  25 on that, but I would say, in general, patients would be</p>
<p style="text-align: right;">Page 135</p> <p>1 said. People respond differently to different things,  2 and we are learning more about that as we -- as people  3 learning about diseases become more sophisticated, that  4 we may not all respond the same way to some particular  5 event in our lives.  6 In the future, we may be able to do that,  7 but we don't now. So you may say in the case of surgery  8 of any kind that someone may respond and do beautifully  9 and have very few complaints regardless of whatever the  10 surgery is, and other people are at greater risk for  11 having an adverse outcome from surgery.  12 We can't -- we -- we know that  13 transpires. How do we go about picking them out? There  14 are some clinical clues, so -- we know there are  15 clinical clues to that.  16 Q. (BY MR. WEBB) Mesh removal surgery being  17 complex, is there any difference between Prolift,  18 Prolift+M, and Prosima?  19 A. Yes, sir, there is. When the mesh arms go  20 through either what's called the sacrospinous ligament  21 or the muscles in the pelvis and the wound heals,  22 getting all of that mesh product out really requires,  23 for lack of a better term, injury to those structures  24 again. Because you have to incise and cut into the  25 structures where the mesh arms have been implanted.</p>	<p style="text-align: right;">Page 137</p> <p>1 looking for something that's much more in their own  2 vocabulary than "foreign body reaction" or  3 "granulation."  4 Q. (BY MR. WEBB) For example, it could cause  5 pain?  6 A. Painful, inflamed. Most people know what  7 inflamed -- so that's not the same as inflammation, but  8 around -- in one sense, it's very similar.  9 Where those products are, the tissue  10 around it is inflamed, or inflammation, maybe, is the  11 best term. I don't know that.  12 But in the people I deal with, in general  13 what has been shown is for all educational things that  14 you and I do, whatever -- whatever it is, it doesn't  15 make it any difference -- you would like to have it at a  16 level so somebody who is in the 8th grade could  17 understand it, and currently that's not a very  18 sophisticated level.  19 Q. Do you get fibrosis and scarring with the  20 implantation of any medical device?  21 MS. THOMPSON: Object to form.  22 A. I am -- do you get scarring with any? Anytime  23 there has to be an entry point to do something, yes,  24 there will be a scar formed.  25 So if you have to puncture it, cut it, do</p>

35 (Pages 134 to 137)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 138</p> <p>1 something to it, the body's reaction is to heal through  2 scar formation. So, yes, that would happen, whether  3 it's an accident or it's a planned surgical  4 intervention, either one.  5 Q. (BY MR. WEBB) You're not saying that every  6 patient is going to have every one of these  7 characteristics, are you?  8 A. No, sir. And I'm saying that some patients  9 won't have any of them.  10 There's a -- the way clinical follow-up  11 appears to occur, the authors who report on adverse  12 events by and large are subspecialists working in  13 referral areas, such as I do, or such as the group at  14 Utah or the group in Cincinnati or Ann Arbor, Michigan.  15 It's generally a referral group.  16 And what we see in them is, in general,  17 women who have an adverse outcome are more likely to go  18 to another doctor than they are to the doctor who  19 performed the original or the index surgery.  20 What that does, then, is once the  21 patients either self-select or perhaps are even referred  22 by the treating doctor -- it doesn't make any  23 difference. But when they self-select, doctors who are  24 in the practice such as I have are more likely to see  25 someone who isn't happy with the outcome, and the</p>	<p style="text-align: right;">Page 140</p> <p>1 circumstances to be well informed enough to tell either  2 the implanting doctor or the patient who is receiving  3 the product exactly what to expect.  4 Q. And these are the same complaints that you  5 made earlier about the Prolift and the Prolift+M?  6 A. Yes, sir.  7 Q. And let me try to summarize it. You complain  8 about the lack and the length of comprehensive study of  9 the patients?  10 A. Yes, sir.  11 MS. THOMPSON: Object to form.  12 A. So the way I interpret what you're commenting  13 on is there wasn't a plan put in place to investigate  14 enough of the variables that relate to -- this is  15 antecedent to the surgery -- who is a good candidate for  16 the surgery, who is the best candidate for the surgery,  17 who is not a candidate for the surgery.  18 The information given and the information  19 for the users is very limited on contraindications. So  20 what's become obvious to the majority of clinicians that  21 isn't in the IFU, for example, or certainly wasn't, is  22 there are a group of people that are outside what was in  23 the IFU. There are people that are older than 18 or 21,  24 that are not pregnant, they're not going to be pregnant,  25 they don't have an active infection. Those are the</p>
<p style="text-align: right;">Page 139</p> <p>1 doctors who like to use whatever the technique is may  2 only see their patients back who are happy with it, and  3 they may not see the ones who have had an adverse  4 outcome. And then the impression is reinforced that  5 actually this works better than most people say because  6 I don't see my patients back complaining.  7 The caveat on that is just because you  8 don't see a patient or I don't see my own patient --  9 just because I don't see them doesn't mean that there  10 isn't an issue. And we know from reports in the  11 literature that between 60 and 80 percent of women who  12 have adverse outcomes are more likely to go see someone  13 who did not do the primary surgery.  14 Q. Ethicon did not provide doctors and patients  15 with complete and accurate information regarding the  16 efficacy, safety, and complications associated with the  17 Prosima devices and their management.  18 That's the same complaint that you had  19 about Prolift and Prolift+M. Is that correct?  20 A. Yes, sir, that's accurate, because there was  21 not a way to do that. The duration of follow-up had not  22 lasted long enough. The factors that were getting  23 followed were relatively narrow in terms of anatomical  24 outcomes and perioperative morbidity, so it wouldn't be  25 practical to collect enough information in those</p>	<p style="text-align: right;">Page 141</p> <p>1 things in the IFU.  2 What they do have, they have a history of  3 fibromyalgia. They smoke excessively. They have  4 diabetes mellitus. They have a variety of other pain  5 complaints, and none of those were isolated out as a  6 potential contraindication to the use of the predict.  7 And I would say that currently, even the  8 most avid advocates of using the products, presuming  9 they were all still available, would come to some  10 consensus that there's a group of women that can be  11 identified by their history who are at high risk for  12 being unhappy with the product, and that those people  13 justifiably need to be advised to consider something  14 else. So that's in the selection criteria. That's not  15 the follow-up.  16 The other thing that has been almost  17 nothing written about is not do you have a complication,  18 it is how do you manage a complication. What's the best  19 way to manage a complication and, ideally, to avoid?  20 So it's a preoperative selection process  21 or elimination for people who are not candidates. It's  22 the identification of a person who is most likely the  23 benefit. So let's presume there are people who do get  24 better. The obligation, then, is let's identify those  25 people. Then we can sit down and have a conversation</p>

36 (Pages 138 to 141)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 142</p> <p>1 with them and feel comfortable that we could say, you  2 know, based on what we know, you actually are a better  3 than average candidate to have this done, but even  4 though you're better than average, these are the things  5 you might expect, and if it occurs, I am capable of  6 managing certain of these things with some degree of  7 knowledge about how likely you are to get better, and we  8 don't have that.</p> <p>9 In addition to, some of the things that  10 are problematic, which were unintended, don't show up  11 immediately, and once you have a foreign body in you,  12 you're at risk for that event to occur for the  13 foreseeable future.</p> <p>14 And I can say that in seeing my own  15 patients now -- because I do have a clinical practice of  16 medicine -- is that there are a group of people who are  17 anxious to know, "What can I expect? Today perhaps I  18 don't really have a complaint, but I know that people  19 have had them, and can you counsel me on what's going to  20 happen?"</p> <p>21 People want to know that. And that would  22 have been a helpful thing.</p> <p>23 Saying that someone has pain is one way  24 to say if you have the surgery, you can have pain.  25 Saying that you may have pain that is lifelong and</p>	<p style="text-align: right;">Page 144</p> <p>1 request sent to me that if they have explant surgery,  2 could the explant material be provided to a lawyer or a  3 particular hospital or somebody for an evaluation. So I  4 have seen patients like that.</p> <p>5 And they may, in fact, have consulted  6 with somebody in advance. I don't know how many do  7 that, but, yes, some people do that.</p> <p>8 Q. And do you have any idea, out of the 100  9 patients that you have seen with mesh, how many were  10 referred to you by lawyers?</p> <p>11 MS. THOMPSON: Object to form.</p> <p>12 A. Actually, I don't know that. I would say my  13 practice is primarily a referral practice, and that's  14 based on a lot of things, almost the least important of  15 which is being referred by a lawyer. It normally is for  16 other reasons. Either they have someone they know that  17 I've cared for or their doctor is someone that I've  18 worked with or know or they've read about it somewhere  19 or another.</p> <p>20 So the exceptional one would be the one  21 who says that my lawyer asked and gave me your name  22 among, whatever, maybe one name or several names, to be  23 seen.</p> <p>24 Q. (BY MR. WEBB) Ethicon failed to disclose the  25 lack of benefit of pelvic organ prolapse surgery using</p>
<p style="text-align: right;">Page 143</p> <p>1 affects the quality of your life and it's practically  2 impossible to manage is a whole different issue.</p> <p>3 And, in fact, we do see there are people  4 that fall into that category. I'm not suggesting  5 everyone does. I don't think anybody suggests that, but  6 there are enough that when you pick up the literature,  7 the group in Cincinnati had 300 patients, the group in  8 Michigan had a hundred and something, the group in  9 Idaho -- or Utah had a hundred and something.</p> <p>10 So there really are a lot of people who  11 have sought attention from experts, and I have no  12 earthly idea, frankly, if any of them or any percentage  13 of them have actually sought legal counsel because of --  14 they're coming to a doctor because they're -- they need  15 some advice on how to get better.</p> <p>16 Q. (BY MR. WEBB) Well, you also know that there  17 are women who have gone to lawyers and then go to  18 doctors after they've been to lawyers?</p> <p>19 A. Yes, sir.</p> <p>20 MS. THOMPSON: Object to form.</p> <p>21 Q. (BY MR. WEBB) Have some of your patients been  22 those type of women, who were referred to you by  23 lawyers?</p> <p>24 A. There have been some women whom I have seen  25 who before they come for a visit, there has been a</p>	<p style="text-align: right;">Page 145</p> <p>1 the Prosima device to physicians and patients.</p> <p>2 For any medical -- well, for any surgery,  3 there's risks and benefits that have to be analyzed on a  4 patient-by-patient basis. Would you agree with that?</p> <p>5 A. I do.</p> <p>6 Q. Do you think that the risk with Prosima  7 outweighed the benefits for most patients?</p> <p>8 A. Yes, sir.</p> <p>9 Q. And have any of your fellow practitioners in  10 your practice used the Prosima device?</p> <p>11 A. No, sir, not that I know of. I will say that  12 in general, when I counsel a patient -- and I've already  13 told you I don't use mesh products for reconstructive  14 surgery. We do do an abdominal sacrocolpopexy.</p> <p>15 When I counsel a patient, it isn't that I  16 tell them that what I can do is magic. I try to point  17 out a reasonable set of expectations. And an example I  18 would use -- and I use it frequently, particularly when  19 I'm lecturing somewhere -- that one of the easiest  20 hernias in the world to fix is in the inguinal canal.  21 So if you or I or anybody in the room or your child or  22 somebody has an inguinal hernia, that's among the  23 easiest operations to do technically.</p> <p>24 It doesn't work all the time. It will  25 never work all the time. And the only goals for that</p>

37 (Pages 142 to 145)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 146</p> <p>1 surgery, primarily, are to fix the hernia and, unless 2 the man wants it, don't remove the testicle or tie off 3 the vas deferens. So don't do those things unless they 4 request it. 5 So, from that standpoint, there are very 6 specific outcome parameters, and it doesn't work all the 7 time. And the two biggest variables outside surgical 8 diagnostic skill and technical skill -- so let's presume 9 they're equal -- the two biggest variables to outcome 10 are how big was the hernia at the beginning, and how 11 long do you follow the patient. So the bigger it was, 12 the more you'll follow them, the more likely they're 13 going to have a recurrence. 14 In women who have problems with the 15 pelvic floor, the issues are considerably more complex. 16 Their bladder may not work. The bowel may not work. 17 Their muscles may be injured. Their nerves may not 18 work. The connective tissue may not work. And they may 19 want all of that to be okay, and for a lot of people, 20 that's a reasonable expectation. 21 There isn't anything that works all the 22 time for every person, and I think all of us recognize 23 that. And everyone recognizes we would like to be able 24 to do better in the context of not causing harm. 25 So we want to do better. We don't want</p>	<p style="text-align: right;">Page 148</p> <p>1 the failure is, whatever we call failure, if it fails 2 20 percent of the time and you want to be able to reduce 3 that failure rate by 10 percent -- I'm sorry, by 4 50 percent, so instead of failing 20 percent of the 5 time, it fails 10 percent of the time. 6 So if that's your goal, there is 7 something called a power analysis that can be calculated 8 to tell you that to learn that, presuming 20 percent of 9 the people have an adverse outcome, and you're going to 10 have some people you treat one way and some the other 11 way, you will have to recruit -- I'm making this up, but 12 I'm going to give an example -- you'll have to recruit 13 200 women, because if you recruit 200, actually 20 won't 14 qualify or won't agree. So you'll end up with 180. 15 Now those 180, you get that 90 in each 16 group, and then you have the power to make a statistical 17 assessment of are those operations similar or not. And 18 depending on the number of variabilities you have, that 19 would determine how long you would have to follow those 20 patients. 21 In my patients -- in an article in 2000, 22 for example, which was not randomized, and I recognize 23 that, it was a group of women I followed, basically 300 24 women, and I had in mind certain variables, but one of 25 the variables which was really important to me -- and it</p>
<p style="text-align: right;">Page 147</p> <p>1 someone to be harmed, and all these issues that I have 2 in the general report which you asked me about relate to 3 the fact that there wasn't enough knowledge acquired 4 and/or shared to be able to tell someone, "Not only are 5 you likely to get better, but what is the likelihood 6 that you could be harmed? And if you are, what's the 7 likelihood we can help you with that?" 8 Those are reasonable things that people 9 would -- I would want to know that. You would want to 10 know that. So those are reasonable things, but we don't 11 have the information on that. That's the -- that's my 12 primary concern. 13 Q. Describe for me a scientific clinical trial 14 demonstrating the safety of the Prosima device that 15 should have been done before its introduction to the 16 commercial market. 17 MS. THOMPSON: Object to form. 18 A. My thought about what would have been helpful 19 to be done is to describe a group of people -- 20 Q. (BY MR. WEBB) How big a group? How big a 21 group? 22 A. There's something called a power analysis that 23 can be done. So the power analysis determines, based on 24 what you think the outcomes are -- for example, if an 25 operation fails 20 percent of the time -- so whatever</p>	<p style="text-align: right;">Page 149</p> <p>1 is to this whole issue -- is how durable is an 2 operation? 3 So if I agree to be operated on, how long 4 can I expect my -- my knee's replaced. How long can I 5 expect it to work? Is it a year? We know what 6 happens -- actually, it's a function of time, so the 7 longer you go, the more likely it isn't going to do 8 whatever you wanted it to do. 9 But until we reported that in this 10 special statistical analysis called a Kaplan-Meier 11 table, it really hasn't been reported in reconstructive 12 surgery. Now, almost everyone uses it to say, "This is 13 the durability of the surgery." That's one important 14 issue. 15 The other thing we've looked at -- and 16 we've learned this as time has gone by -- there are 17 going to be adverse events with surgery. There is no 18 way to avoid that. 19 My mother died after an operation, so I'm 20 acutely aware of that. There are adverse events after 21 surgery. What I want to know, can I avoid it, and if I 22 can't avoid it, how can I identify it and correct it? 23 So we are learning about that. 24 And what I do, I know that there is a 25 little group of women who will acquire a pain complaint</p>

38 (Pages 146 to 149)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 150</p> <p>1 they did not have before surgery, and it is specific to</p> <p>2 what I do, and I know when it shows up, and I know the</p> <p>3 presenting characteristics, and I know how to take care</p> <p>4 of it.</p> <p>5 So if I talk to someone about that, I can</p> <p>6 say, one woman out of 100, about, will have this very</p> <p>7 specific adverse event, which I can recognize and I can</p> <p>8 tell you how to manage it, but I cannot avoid it. I</p> <p>9 cannot avoid it all the time. It's not possible to do</p> <p>10 that.</p> <p>11 And when the patients know that, even</p> <p>12 when they have the adverse outcome, they have the</p> <p>13 knowledge that that's something I really do know about,</p> <p>14 and if it bothers them, I can manage it. That's a</p> <p>15 comfort to the doctor and to the patient. And in these</p> <p>16 circumstances, the thing that's different is these are</p> <p>17 complications that in general are different than what</p> <p>18 we've seen before and, frankly, doctors are still</p> <p>19 working out how to manage them most effectively.</p> <p>20 There's a whole spectrum of thought on</p> <p>21 that. If you have pain after mesh, some doctors</p> <p>22 advocate taking out the entire mesh. Well, the truth is</p> <p>23 there's a tiny group of people technically skilled</p> <p>24 enough to do that without really creating a problem.</p> <p>25 And even if they are skilled enough to do it, there</p>	<p style="text-align: right;">Page 152</p> <p>1 my question before you start.</p> <p>2 A. I'm sorry.</p> <p>3 Q. Tell me the length of this hypothetical</p> <p>4 clinical trial demonstrating the safety of the Prosima</p> <p>5 device that should have gone on before its introduction</p> <p>6 to the commercial market.</p> <p>7 A. Depending on the outcome variables, it's</p> <p>8 possible to understand the perioperative complications</p> <p>9 very quickly. So then you just have to decide how many</p> <p>10 people do you need to recruit to do it. So the</p> <p>11 perioperative complications can be done quickly.</p> <p>12 The issue about picking the right patient</p> <p>13 and have comparable groups -- so you've used the same</p> <p>14 selection criteria, and then if you're looking for the</p> <p>15 onset of anatomic failure, most of the anatomical</p> <p>16 failures that are not technically related -- that means</p> <p>17 the operation wasn't executed well or was</p> <p>18 underdiagnosed -- so if you eliminate the immediate</p> <p>19 postoperative failures -- so somebody is in surgery</p> <p>20 today and a week from now or a month from now the</p> <p>21 surgery hasn't worked. So let's eliminate those.</p> <p>22 Now it's somebody who had initially a</p> <p>23 good response but have a recurrence. That takes at</p> <p>24 least one year, and even that probably isn't right.</p> <p>25 Several years, depending on what people -- that's for</p>
<p style="text-align: right;">Page 151</p> <p>1 still is a risk that what they do will make the patient</p> <p>2 worse than they already are.</p> <p>3 So we are still working on how to</p> <p>4 identify and manage it, and that's the dilemma. And I</p> <p>5 don't think I'm suggesting that that was a conscious</p> <p>6 decision on anyone's part to say, you know, we're going</p> <p>7 to hurt people. I don't believe that. I don't think</p> <p>8 anyone wants to do that. But the unintended consequence</p> <p>9 is people were hurt and could you -- could, not you</p> <p>10 personally -- could people have anticipated that?</p> <p>11 Frankly, probably not eliminated, but done everything</p> <p>12 possible to make that less likely to occur. And if it</p> <p>13 were to occur, to have a strategy to manage it.</p> <p>14 And this is something I know a lot about</p> <p>15 because I see these people, and, frankly, the people I</p> <p>16 see almost never have come to me saying, "I want to sue</p> <p>17 someone."</p> <p>18 That's the exception. They come to me</p> <p>19 with their spouse because their life has been changed.</p> <p>20 MR. WEBB: Objection; nonresponsive.</p> <p>21 Q. (BY MR. WEBB) Tell me the length of this</p> <p>22 hypothetical clinical trial that Ethicon should have put</p> <p>23 in place --</p> <p>24 A. Well --</p> <p>25 Q. -- to demonstrate the safety -- let me finish</p>	<p style="text-align: right;">Page 153</p> <p>1 the anatomy.</p> <p>2 Then because some of the problems are</p> <p>3 actually not known about -- they may be anticipated but</p> <p>4 you don't know them, pain complaints, contraction of the</p> <p>5 mesh, and if it contracts, how long does it take to</p> <p>6 create a problem -- you can't really know that until you</p> <p>7 set an arbitrary time limit, and that could be one year</p> <p>8 or two years. But what most doctors would then do who</p> <p>9 are involved in a trial, they would say, "Well, I'm</p> <p>10 going to follow these patients later because what I may</p> <p>11 find out is all of the problems came up in the first six</p> <p>12 months, then after six months, there really is nothing,"</p> <p>13 or, "What I really found out is some of them came up at</p> <p>14 six months or a year, but, you know, really, the longer</p> <p>15 we followed them, there's some other things."</p> <p>16 So that's not practical, to follow</p> <p>17 somebody indefinitely, but somewhere between 12 and</p> <p>18 24 months would be a reasonable start on that, along</p> <p>19 with strict criteria on the patients for whom you can</p> <p>20 use the procedure.</p> <p>21 Currently, when I read these reports in</p> <p>22 both the Prosima and the Prolift, it could have been for</p> <p>23 a woman who has had prior surgery and failed, a woman</p> <p>24 who has had no prior surgery, a woman who has a</p> <p>25 hysterectomy, a women who doesn't have a hysterectomy, a</p>

39 (Pages 150 to 153)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 154</p> <p>1 woman -- so the variables just mount and mount up, and  2 one of the issues which these documents have shown is:  3 That's important to know, are they going to have a  4 hysterectomy and, what kind of incision? That was  5 learned on the fly, sort of.  6 So there are so many variables to look  7 at, but if you just pick a few of them -- selection,  8 avoiding complications, managing complications,  9 anatomical outcome, acquisition of complaints -- that  10 would take at least, for recruitment -- the recruitment  11 would take at least a year. The follow-up would take at  12 least a year. And then, depending on how you do the  13 power analysis, the recruitment could take longer.  14 That's one of the issues now with these  15 522 things that some companies are going to do is the  16 power analysis tells them they have to recruit so many  17 people, that one surgeon can't be -- can't do it. It  18 has to be a multicenter study to do it. Those things  19 all add complexity and expense to it.  20 Q. Out of the 100 patients that you've seen who  21 have had complications with mesh, how many of them do  22 you think are surgeon's technique problems?  23 A. I wouldn't allocate the technique problem,  24 frankly, to any of them with the following exceptions.  25 If I see someone -- or someone I operate on, let's</p>	<p style="text-align: right;">Page 156</p> <p>1 teach them what to do, that's challenging.  2 MR. WEBB: Objection; nonresponsive.  3 Q. (BY MR. WEBB) You said you personally have  4 examined, diagnosed, and treated approximately 100  5 patients with mesh complications and removed some mesh  6 from at least 70 women.  7 How many out of those patients are -- do  8 you think are directly related to physician technique?  9 A. What I tried --  10 MS. THOMPSON: Asked and answered.  11 A. I'm sorry. What I tried to explain is what I  12 think would be a physician error, and the ones that I  13 know are physician errors, I haven't seen them, where  14 the mesh was put into something.  15 Q. (BY MR. WEBB) So you're saying zero out of  16 the 100. Is that what you're saying?  17 A. No, sir. What I'm saying is --  18 Q. I'm asking you for a number, Doctor. If you  19 can give me a number, say it. If you can't, just say  20 you can't give me a number.  21 MS. THOMPSON: Objection.  22 Q. (BY MR. WEBB) We're going to be here until  23 9:00 at the rate we're going.  24 A. I don't --  25 MS. THOMPSON: Objection to that --</p>
<p style="text-align: right;">Page 155</p> <p>1 say -- so I'm not always pointing -- to say somebody  2 else did it. I could be the one who does that.  3 For example, this one article you asked  4 me to confirm earlier today about placing a TVT in the  5 bowel, that was my patient. So it wasn't somebody  6 else's patient. It was my patient.  7 So the surgeon contribution to the  8 problem frequently is identified immediately. The  9 product is put in the wrong place, in the bladder or in  10 the bowel. When I say "immediately," either right then  11 or within the next day or two. So there can be a  12 surgeon error. There's no doubt about it.  13 The other thing that's much more subtle,  14 which this anatomic report in the Prosima, where they  15 took a group of people and took them to the anatomy lab,  16 that's much more subtle because you are having a surgeon  17 operate in a space where you cannot see what they're  18 doing.  19 And I taught cadaver labs, and I've  20 operated on thousands of people. A cadaver lab and  21 operating on real people have some similarities, but  22 doing vaginal reconstructive surgery on a cadaver -- and  23 some of these cadavers are 90 years old or 92 years  24 old -- that is extremely difficult to -- not only to do,  25 but for a teacher to watch someone else and effectively</p>	<p style="text-align: right;">Page 157</p> <p>1 A. I don't know. I'm sorry.  2 MS. THOMPSON: -- comment.  3 MR. WEBB: Well, there's a point when if  4 he's just going to sit there and just -- you know, just  5 blabber and not answer the question, then I'm going to  6 cut him off. Do you understand?  7 MS. THOMPSON: I think you can cut him  8 off, but we're not going to be here until 9:00  9 regardless.  10 MR. WEBB: Let's put it this way, then --  11 MS. THOMPSON: We're going to be here --  12 MR. WEBB: -- I'm going to keep going  13 until the maximum time, then, if that's --  14 MS. THOMPSON: Okay. Well, you've got --  15 MR. WEBB: -- the way we're going to play  16 the game.  17 MS. THOMPSON: -- two hours, and we'll go  18 the two hours.  19 MR. WEBB: No. I've got three hours is  20 what I've got on each one of these.  21 MS. THOMPSON: No. You have three hours  22 on the first and two hours on the second.  23 MR. WEBB: Okay. Well, I -- we'll go  24 until every minute of it is gone if that's the way --  25 MS. THOMPSON: Okay.</p>

40 (Pages 154 to 157)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 158</p> <p>1 MR. WEBB: -- you're going to play it.  2 MS. THOMPSON: All right. You've got  3 about --  4 THE WITNESS: I'm comfortable -- if I'm  5 not answering effectively, tell me. I'm fine to stop  6 and try to answer it. I'm not trying to avoid your  7 question. So I'm happy to try to respond, and just ask  8 me to do that.  9 Q. (BY MR. WEBB) Tell me why Ethicon did not  10 exercise due diligence in the design and development of  11 the Prosima mesh.  12 A. I think it's the things we've mentioned  13 already about the unknown, putting something in these  14 spaces and leaving them there and what the potential  15 benefit or non-benefit is to putting a support device in  16 it.  17 Q. Tell my why Ethicon lacked scientific rigor in  18 the testing and reporting of its pelvic floor products,  19 including the use of Gynemesh.  20 A. Because we don't have the information about  21 prospective clinical trials on how the products behaved  22 in people.  23 Q. Ethicon did not heed the warnings from the  24 hernia and gynecologic literature relating to the use of  25 polypropylene mesh?</p>	<p style="text-align: right;">Page 160</p> <p>1 A. Yes, sir. People have varying skill levels to  2 use -- and this is a sophisticated operation, and there  3 are varying skill levels, and people, frankly, don't  4 have the skill to do that.  5 Q. And you said earlier -- this says, "Ethicon  6 inappropriately marketed its prolapse mesh products to  7 all physicians."  8 Yet you told me that the hospitals were  9 the ones that bought the products. Is that correct?  10 A. Yes, sir.  11 Q. And --  12 A. I beg your pardon. The hospital may buy it at  13 the request of the physician, for example. I just -- I  14 don't think there's a direct transaction between the  15 doctor and --  16 Q. Well, and it also may be that hospitals enter  17 into contracts and they tell you what products are going  18 to be made available to you. Correct?  19 A. That's entirely true.  20 Q. "After the products were used in a general  21 clinical setting, Ethicon did not systematically monitor  22 their products for safety or efficacy or evaluate  23 physician feedback."  24 What do you base that statement on?  25 A. I didn't see any documents to indicate that.</p>
<p style="text-align: right;">Page 159</p> <p>1 A. The hernia wall -- the abdominal wall or the  2 inguinal canal are sterile areas, and mesh is used in a  3 sterile area. And if it -- if there's wound infection,  4 mesh isn't used in those areas. And the vaginal canal  5 isn't sterile. It's contaminated.  6 So those are major differences. And  7 there have been reported incidences of mesh shrinking in  8 the abdomen and pain associated with it.  9 Q. If Ethicon had properly tested its products,  10 certain problems and complications would have been  11 identified before they were used in a clinical setting.  12 Tell me, if you haven't already, what  13 problems and what complications would have been  14 identified before they were used in a clinical setting.  15 A. Well, from a clinical use, so the clinical --  16 the evaluation before clinicians in general used them  17 would be more knowledge about erosion rates, pain,  18 contraction, and possible effects on bowel and bladder  19 function. And in the case of exposure in the vaginal  20 canal, possible injury to the sexual partner or new  21 onset pain complaints.  22 Q. "Ethicon inappropriately marketed its prolapse  23 mesh products to all physicians."  24 Is this the same answer that you would  25 give me as you did on the Prolift and Prolift+M?</p>	<p style="text-align: right;">Page 161</p> <p>1 Q. Did you ask for any documents on that?  2 A. No, sir.  3 Q. Were -- did you ask the plaintiffs' lawyer,  4 who provided documents to you, to give you documents  5 specifically about Ethicon's monitoring of the products  6 for safety or efficacy or evaluate physician feedback?  7 A. No, sir.  8 Q. The problems associated with the Prosima  9 device are inherent in the concept and design and occur  10 even when the device is placed properly.  11 Is this the same complaints that you had  12 about the Prolift and the Prolift+M?  13 A. It's similar because it uses the same mesh  14 product. The -- the placement is different, but it's  15 still the same mesh product.  16 Q. Is there anything about the placement that  17 would be different about the Prolift or Prolift+M?  18 A. Yes, sir. Theoretically, it would be a safer  19 placement for Prosima.  20 Q. Why do you say, "In Carey's randomized trial  21 comparing traditional anterior and posterior surgery  22 with the Prosima precursor, the authors failed to  23 demonstrate any improvement in the treatment of  24 prolapse"?  25 A. Those are his conclusions. Well, I mean, when</p>

41 (Pages 158 to 161)



Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 162</p> <p>1 you look at the data, that's -- that's what it showed.  2 He showed approximately a 20 percent persistent  3 anatomical defect in both groups of patients.  4 So there were -- it was a randomized  5 trial in which it didn't show that one was appreciably  6 better than the other.  7 THE REPORTER: I'm sorry. It didn't --  8 THE WITNESS: It was a randomized trial  9 which did not show that one was appreciably better than  10 the other.  11 THE REPORTER: Try to keep your voice up  12 for me, please. I'm sorry.  13 Q. (BY MR. WEBB) You make a statement saying  14 that, "During implantation, tension is placed on the  15 mesh as the instruments are placed in the pockets of the  16 straps, not only during implantation, but after the  17 Prosima straps are put under some tension, which may  18 ultimately lead to mesh bunching, wrinkling,  19 deformation."  20 Do you know whether or not that actually  21 happens?  22 A. I don't know --  23 MS. THOMPSON: Object to form.  24 A. I don't know that it happens every time, but I  25 know from the standpoint of, for example, using a</p>	<p style="text-align: right;">Page 164</p> <p>1 So it's possible I -- I apologize. I  2 didn't look specifically for that, but I did read it.  3 There was information for use, which I highlighted and  4 used that in preparing the report.  5 Q. What did the IFU say about the use of this  6 product in women with a history of chronic pelvic pain?  7 A. I'm not sure it said anything. It said do not  8 use it in women with vaginal infections. It said that  9 the product stays soft and pliable. I don't recall that  10 it said anything about the use in women with chronic  11 pelvic pain.  12 It commented on using the product in  13 women who have certain degrees of pelvic organ prolapse  14 but that degree wasn't specifically quantified, nor the  15 reference point for its -- what was it, for the POP-Q  16 stage, or was it something else -- which people would  17 use in common language to know which candidates are  18 best.  19 MR. WEBB: Let's take a short break.  20 THE VIDEOGRAPHER: Going off the record,  21 the time is 2:49.  22 (Recess from 2:49 p.m. to 2:56 p.m.)  23 THE VIDEOGRAPHER: Back on the record.  24 This marks the beginning of Disc No. 4. The time is  25 2:56.</p>
<p style="text-align: right;">Page 163</p> <p>1 midurethral sling, which I've done hundreds of times,  2 that it -- what you intend to do doesn't always go  3 exactly the way you want to do it. So the mesh may lay  4 flat temporarily and it may not, and you have to  5 manipulate it to get it into position.  6 So it isn't -- it doesn't always lie  7 exactly in the position you would like it to be, and  8 when you work with it in a space where it's actually  9 remote from where you can see, you have to put some  10 degree of tension on it in order to try to flatten it or  11 straighten it out.  12 Q. (BY MR. WEBB) Have you actually read the  13 Prosima IFU?  14 A. Yes, sir.  15 Q. When did you read the Prosima IFU?  16 A. I read it twice. I read it sometime back in  17 January, and I read it again over the weekend.  18 Q. Is it in the documents that you provided us  19 today?  20 A. I thought it was, but it may not be. I may  21 have taken it out, actually, and failed to put it back  22 in there. But the answer is, yes, I did read it and I  23 highlighted it, and I thought that I had put it in here,  24 and what may have happened is it may be in my study at  25 home.</p>	<p style="text-align: right;">Page 165</p> <p>1 Q. (BY MR. WEBB) Dr. Shull, the time that you  2 spent with an attorney representing the plaintiffs, did  3 you include the time that you were talking about Prosima  4 in that time? Was that total time?  5 A. Is that on the time sheet that I gave you  6 there, or is that for other patients the other day?  7 Q. No. I'm talking about the time you spent  8 yesterday and today. Was there separate --  9 A. Yes.  10 Q. -- time that you spent discussing just Prolift  11 and Prolift+M that you told me about and separate time  12 for just Prosima, or was it just all together?  13 A. It was in the aggregate.  14 Q. Are there any complications using native  15 tissue that you do not have with vaginal mesh?  16 A. There could be the way I do it. For example,  17 in the specific technique that I use with uterosacral  18 ligaments, entrapping a nerve near one of the ligaments  19 on one side of the pelvis occurs about one time out of  20 100, and I think -- I know that is specific to the  21 technique that I use. I don't know that that occurs  22 with either the Prolift or the Prosima. So that may be  23 one difference.  24 Another difference is when I do the  25 reconstructive surgery transvaginally, I frequently use</p>

42 (Pages 162 to 165)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 166</p> <p>1 some sutures which do not dissolve -- not all, but I use  2 some Ethibond sutures. Those may end up being exposed  3 in the vaginal tissue at a time after a normally  4 expected recovery interval of six to 12 weeks. So a  5 patient could come back in months or, frankly, even in  6 several years or more and say they have some vaginal  7 spotting, and I may see a suture exposed through the  8 vaginal skin, which almost always can be removed in the  9 office.</p> <p>10 There are a few exceptions where it's so  11 high in the vaginal canal that it's better to do it with  12 what's called local MAC anesthesia, where somebody  13 inhales something and gets some IV sedation. So that  14 occurs occasionally. And that's a consequence of my  15 intentional decision to use sutures that don't dissolve.</p> <p>16 Q. Have you ever reviewed any animal testing  17 either on Prolift, Prolift+M, or Prosima?</p> <p>18 MS. THOMPSON: Object to form.</p> <p>19 A. Have I personally used it?</p> <p>20 Q. (BY MR. WEBB) Have you personally reviewed  21 any animal testing on Prolift, Prolift+M, or Prosima?</p> <p>22 A. I don't think so.</p> <p>23 Q. Would you expect a product to look different  24 after implantation than it did when it is explanted?</p> <p>25 A. Excuse me. Would I expect it to look</p>	<p style="text-align: right;">Page 168</p> <p>1 EXAMINATION</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. I have a few questions, Dr. Shull.</p> <p>4 When you asked for the literature  5 regarding Prolift and Prolift+M, did you ask for all of  6 the literature available?</p> <p>7 A. Yes, I did.</p> <p>8 Q. And is the same true for Prosima?</p> <p>9 A. Yes, I did.</p> <p>10 Q. And did you personally review and critically  11 assess this literature?</p> <p>12 A. Yes, I did.</p> <p>13 Q. Were you aware of any kind of screening  14 process that was used to select the articles that we --  15 were sent to you?</p> <p>16 A. No, I'm not. I wasn't.</p> <p>17 Q. And did the literature that you reviewed and  18 critically assessed, did it include literature that, at  19 least from the author's conclusions, were both favorable  20 and unfavorable to your opinions?</p> <p>21 A. Yes. I think in every one I read, the authors  22 found something positive to say about the products, and  23 in every one I read, particularly in the discussions,  24 there was information to say there -- there needed to be  25 longer follow-up, and there are other items that could</p>
<p style="text-align: right;">Page 167</p> <p>1 different?</p> <p>2 Q. Would you expect a product that's been  3 implanted to be -- to look different than that when  4 you -- when it's explanted from the body?</p> <p>5 A. Yes, sir.</p> <p>6 Q. Especially something with mesh that's designed  7 to have ingrowth into the mesh?</p> <p>8 A. Yes, sir. It may look different from  9 several -- for several reasons. One of them could be  10 adjacent tissue. One could be a change in the geometry  11 or the surface area of the product.</p> <p>12 Q. Do you consider it the responsibility of a  13 surgeon to keep current on the medical literature in  14 their area of expertise or their area of practice?</p> <p>15 A. Yes, sir.</p> <p>16 Q. Did Ethicon tell the doctors in the  17 instructions for use document for Prosima that training  18 on the use of Prosima was recommended and available?</p> <p>19 A. I believe the wording would be you could  20 request it -- yes, it was available if you wanted it. I  21 don't think it was indicated it was required, but it  22 was -- if you wanted it, it was available.</p> <p>23 MR. WEBB: I'll pass the witness.</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 169</p> <p>1 be learned about.</p> <p>2 Q. You were asked questions about your experience  3 with mesh complications. Are your colleagues and the  4 fellows at Scott &amp; White also seeing patients with mesh  5 complications?</p> <p>6 MR. WEBB: Objection.</p> <p>7 A. Yes, they are.</p> <p>8 Q. (BY MS. THOMPSON) And are you aware,  9 generally, of the mesh complications that are being seen  10 in your department by others?</p> <p>11 A. In general, that's true. We have what's  12 called an M&amp;M conference every month, and we may talk  13 about specific issues. They could be related to mesh  14 exposure, or when we look at the operative schedule, we  15 frequently discuss what the day is like, and we'll know  16 that someone is going to be working on a mesh  17 explantation, for example.</p> <p>18 Q. And your colleagues are also removing mesh  19 devices at Scott &amp; White?</p> <p>20 A. Yes.</p> <p>21 MR. WEBB: Objection; form.</p> <p>22 A. That's correct.</p> <p>23 Q. (BY MS. THOMPSON) You were asked questions  24 about whether you considered yourself an expert in  25 certain fields. Do you remember that line of</p>

43 (Pages 166 to 169)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 170</p> <p>1 questioning?</p> <p>2 A. Yes, I do.</p> <p>3 Q. As a clinician, do you have familiarity with</p> <p>4 the medical literature relating to the material and</p> <p>5 chemical properties of polypropylene mesh and their</p> <p>6 clinical significance?</p> <p>7 A. I think I do.</p> <p>8 Q. And are many of those articles cited in your</p> <p>9 report as providing some basis for your opinions?</p> <p>10 A. Certainly the background information provides</p> <p>11 informed -- information for me to come to a conclusion,</p> <p>12 and I would have to look specifically at the references.</p> <p>13 Do you have one particular one in mind? I'd be glad to</p> <p>14 look at it.</p> <p>15 Q. No. I was just speaking generally. But let's</p> <p>16 look at the -- let's look at your Prolift report, if you</p> <p>17 have that handy.</p> <p>18 A. Well, I have the articles, including the -- I</p> <p>19 think I had some separate articles this morning. Did I</p> <p>20 leave some other articles with you this morning? May I</p> <p>21 see those just a moment -- or maybe from after lunch?</p> <p>22 Thank you.</p> <p>23 These three articles, to ask -- to answer</p> <p>24 your question, at least in part, this article published</p> <p>25 in 2004 on "Host response after reconstruction of</p>	<p style="text-align: right;">Page 172</p> <p>1 clinical practice, review IFUs or instructions for use</p> <p>2 for various products?</p> <p>3 A. Yes, ma'am, particularly on the ones I use.</p> <p>4 Q. And is the information contained in the IFU,</p> <p>5 including the warnings section, important to you and</p> <p>6 other physicians in making treatment decisions?</p> <p>7 A. It's important in knowing globally what to</p> <p>8 expect, and ideally it should be in patient selection,</p> <p>9 for example.</p> <p>10 Q. And is the information contained in the IFU,</p> <p>11 including the warnings, important to you and other</p> <p>12 physicians when you are obtaining an informed consent</p> <p>13 from patients?</p> <p>14 A. Yes.</p> <p>15 Q. Do you have an opinion as to whether the</p> <p>16 Prolift and Prolift+M devices are defective from a</p> <p>17 clinical standpoint?</p> <p>18 MR. WEBB: Objection; form.</p> <p>19 A. Well, from a clinical standpoint, what I see</p> <p>20 is the consequence of mesh that is -- after implantation</p> <p>21 becomes reduced in area with tight bands or exposure or</p> <p>22 tenderness to palpation, leading to clinical</p> <p>23 consequences of pain, exposure, and other issues.</p> <p>24 So from that standpoint, I feel that I</p> <p>25 have a level of expertise for being able to obtain the</p>
<p style="text-align: right;">Page 171</p> <p>1 abdominal wall defects with a porcine dermal collagen in</p> <p>2 a rat model" -- I beg your pardon -- that animal also</p> <p>3 had -- in addition to Pelvicol, had Prolene. So the</p> <p>4 investigators looked at a xenograft and a synthetic</p> <p>5 material and looked at a variety of microscopic</p> <p>6 parameters that could be evaluated, including</p> <p>7 inflammatory response and how fast the inflammatory</p> <p>8 response went away, and it looked at collagen</p> <p>9 deposition. So that would be in an animal model, not a</p> <p>10 human.</p> <p>11 Q. And looking at footnotes, for example, 10, 11,</p> <p>12 12, 13, 14 -- I'm just looking at the titles of those</p> <p>13 articles. That would be Page 7 of your report. And I</p> <p>14 see articles relating to bacterial colonization, to</p> <p>15 shrinkage, to contraction, to lightweight and large</p> <p>16 porous concepts, the material's characterization of</p> <p>17 explant polypropylene hernia meshes, the pathology of --</p> <p>18 pathological findings of transvaginal polypropylene</p> <p>19 slings.</p> <p>20 Are those just examples of literature</p> <p>21 that discusses the material properties of polypropylene</p> <p>22 and their clinical consequences?</p> <p>23 MR. WEBB: Objection; form.</p> <p>24 A. Yes.</p> <p>25 Q. (BY MS. THOMPSON) Do you, as part of your</p>	<p style="text-align: right;">Page 173</p> <p>1 history, do the exam, and correlate the exam and the</p> <p>2 historical information.</p> <p>3 Q. (BY MS. THOMPSON) And are those problems with</p> <p>4 the Prolift and Prolift+M devices discussed in your</p> <p>5 report?</p> <p>6 A. Yes.</p> <p>7 Q. And are they based on the -- your knowledge</p> <p>8 and review of the peer-reviewed medical literature as</p> <p>9 well as your experience?</p> <p>10 A. That's correct.</p> <p>11 Q. And would the same be true for the Prosima</p> <p>12 device?</p> <p>13 A. In the patients in whom I have seen -- and for</p> <p>14 certain the one I've operated on -- and I don't know if</p> <p>15 I've operated on more -- yes, I have personal experience</p> <p>16 in listening to, evaluating, and managing an explant in</p> <p>17 someone with Prosima.</p> <p>18 Q. And do the Prolift and Prolift+M devices and</p> <p>19 the Prosima behave similarly to other transvaginal</p> <p>20 polypropylene mesh kits that you're familiar with and</p> <p>21 that are reported in the medical literature?</p> <p>22 MR. WEBB: Objection; form.</p> <p>23 A. To the best of my knowledge, they're similar.</p> <p>24 Q. (BY MS. THOMPSON) So literature describing</p> <p>25 complications of transvaginally placed prolapse mesh in</p>

44 (Pages 170 to 173)

Bobby Lewis Shull, M.D.

<p style="text-align: right;">Page 174</p> <p>1 general would also apply to Ethicon's products?</p> <p>2 MR. WEBB: Objection; form.</p> <p>3 A. For the --</p> <p>4 Q. (BY MS. THOMPSON) Is that true?</p> <p>5 A. For the trocar-based devices, I believe that's</p> <p>6 true. For the non-trocar based, I'm not familiar that</p> <p>7 there is a another product that is similar to Proxima.</p> <p>8 There may be, but I'm not familiar with it.</p> <p>9 Q. You were asked some questions about Ethicon's</p> <p>10 marketing to physicians. Did Ethicon market -- even if</p> <p>11 it didn't sell to physicians, did Ethicon market its</p> <p>12 products to physicians based on your review of the</p> <p>13 Ethicon documents and your knowledge of attending</p> <p>14 meetings and dealing with sales representatives of</p> <p>15 companies?</p> <p>16 MR. WEBB: Objection; form.</p> <p>17 A. I think I can answer it two ways. In review</p> <p>18 of the information obtained in the documents I have, it</p> <p>19 looks as if there were presentations prepared and</p> <p>20 reviewed to be able to discuss with potential customers,</p> <p>21 the doctors.</p> <p>22 And when I go to scientific meetings,</p> <p>23 this is -- in general, whether it's an international</p> <p>24 meeting or a state or a domestic American meeting,</p> <p>25 there -- frequently, if not always, there are exhibits</p>	<p style="text-align: right;">Page 176</p> <p>1 EXAMINATION</p> <p>2 BY MR. WEBB:</p> <p>3 Q. You said that -- you were asked some questions</p> <p>4 about colleagues at Scott &amp; White who are also removing</p> <p>5 mesh devices. Do you remember that question?</p> <p>6 A. Yes, sir, I do.</p> <p>7 Q. Do you also have colleagues at Scott &amp; White</p> <p>8 that are implanting mesh devices?</p> <p>9 MS. THOMPSON: Object to form.</p> <p>10 A. I can answer that in two ways. I have</p> <p>11 associates who do abdominal sacrocolpopexy, and they'll</p> <p>12 use a synthetic mesh for the abdominal sacrocolpopexy.</p> <p>13 I have colleagues both in urology and GYN</p> <p>14 who may do that. I have colleagues in urology and GYN</p> <p>15 who use midurethral slings, and they're mesh products.</p> <p>16 So in those two categories, the answer is, yes, there</p> <p>17 are people who work with me who are doing that.</p> <p>18 I don't -- to the best of my knowledge, I</p> <p>19 don't have anyone in our department who is using mesh</p> <p>20 kits transvaginally, or even the mesh applique, for</p> <p>21 prolapse. I don't think our urology group currently</p> <p>22 has.</p> <p>23 I believe that our urology group, for</p> <p>24 which I really don't have any input on anything about it</p> <p>25 particularly -- I believe they previously had one member</p>
<p style="text-align: right;">Page 175</p> <p>1 that are sponsored by various companies in industry to</p> <p>2 let the registrants know what is available to be</p> <p>3 purchased.</p> <p>4 And depending on what the product is,</p> <p>5 there may be videos. There may be demonstrations on a</p> <p>6 model of some sort, and that's particularly true of</p> <p>7 products that require surgical implantation.</p> <p>8 In addition to having 3D models and</p> <p>9 samples of the product available for people to work with</p> <p>10 and the videos, there may be one or more physicians who</p> <p>11 have used that particular product and may lead a</p> <p>12 discussion and/or show a demonstration about how to use</p> <p>13 the products.</p> <p>14 So I would say that those aren't -- those</p> <p>15 demonstration aren't limited to a certain segment of the</p> <p>16 people who register for the meeting -- let's use the</p> <p>17 American College of Obstetricians and Gynecologists, for</p> <p>18 example. So anyone can participate in listening to</p> <p>19 and/or perhaps even trying, on the model, different</p> <p>20 things that are being shown.</p> <p>21 MS. THOMPSON: I have no further</p> <p>22 questions.</p> <p>23 MR. WEBB: Let me have a follow-up here.</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 177</p> <p>1 who did use transvaginal mesh, but I don't know how</p> <p>2 frequently, and I don't believe that particular person</p> <p>3 works with us anything longer.</p> <p>4 MR. WEBB: That's all I have.</p> <p>5 THE WITNESS: Thank you.</p> <p>6 THE VIDEOGRAPHER: This concludes the</p> <p>7 deposition of Dr. Bob Shull. Going off the record, the</p> <p>8 time is 3:15.</p> <p>9 (Whereupon the deposition concluded at</p> <p>10 3:15 p.m.)</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

45 (Pages 174 to 177)

Bobby Lewis Shull, M.D.

Page 178		Page 180	
1	ACKNOWLEDGMENT OF DEPONENT	1	-----
2		2	ERRATA
3	I, _____, do hereby	3	-----
4	certify that I have read the foregoing pages, and that	4	PAGE LINE CHANGE
5	the same is a correct transcription of the answers given	5	REASON: _____
6	by me to the questions therein propounded, except for	6	_____
7	the corrections or changes in form or substance, if any,	7	REASON: _____
8	noted in the attached Errata Sheet.	8	_____
9		9	REASON: _____
10	BOBBY LEWIS SHULL, M.D. DATE	10	_____
11		11	REASON: _____
12		12	_____
13		13	REASON: _____
14		14	_____
15	Subscribed and sworn to before me this ____ day of	15	REASON: _____
16	_____, 20__.	16	_____
17	My commission expires: _____	17	REASON: _____
18	_____	18	_____
19	Notary Public	19	REASON: _____
20		20	_____
21		21	REASON: _____
22		22	_____
23		23	REASON: _____
24		24	_____
25		25	REASON: _____

  

Page 179		Page 181	
1	CERTIFICATE	1	LAWYER'S NOTES
2		2	PAGE LINE
3	I, Steven Stogel, a Certified Shorthand Reporter in	3	_____
4	and for the State of Texas, do hereby certify that BOBBY	4	_____
5	LEWIS SHULL, M.D., the witness whose deposition is	5	_____
6	hereinbefore set forth, was duly sworn by me and that	6	_____
7	such deposition is a true record of the testimony given	7	_____
8	by the witness.	8	_____
9	I further certify that I am neither related to or	9	_____
10	employed by any of the parties in or counsel to this	10	_____
11	action, nor am I financially interested in the outcome	11	_____
12	of this action.	12	_____
13	In witness whereof, I have hereunto set my hand and	13	_____
14	seal this 18th day of March, 2016.	14	_____
15		15	_____
16		16	_____
17		17	_____
18	STEVEN STOGEL	18	_____
19		19	_____
20		20	_____
21		21	_____
22		22	_____
23		23	_____
24		24	_____
25		25	_____

46 (Pages 178 to 181)



Bobby Lewis Shull, M.D.

Page 182

<b>A</b>				
<b>aaron</b> 22:7	<b>acted</b> 120:15	<b>agent</b> 79:20	106:6 109:5	161:21
<b>abdomen</b> 50:13	<b>action</b> 179:11,12	<b>ages</b> 48:19	123:15 124:13,20	<b>antibiotic</b> 79:14
61:22 159:8	<b>active</b> 140:25	<b>aggregate</b> 126:16	124:23 125:1,8,25	<b>antibiotics</b> 81:11
<b>abdominal</b> 16:13	<b>activities</b> 132:3	128:25 165:13	126:5 127:13,17	<b>anticipate</b> 77:13
35:22 47:11 57:25	<b>activity</b> 131:19	<b>ago</b> 58:17 68:6,7	139:23 152:15	<b>anticipated</b> 125:22
73:15,18 85:8	<b>actual</b> 21:14 23:23	97:24 129:24,25	154:9 162:3	151:10 153:3
86:7,7 118:11	<b>acutely</b> 149:20	<b>agree</b> 45:18 46:21	<b>anatomically</b> 59:11	<b>anxious</b> 142:17
145:14 159:1	<b>add</b> 154:19	47:20 48:9 52:10	<b>anatomy</b> 48:14,17	<b>anybody</b> 71:22
171:1 176:11,12	<b>adding</b> 50:7	63:24 64:1 83:20	49:12,14 60:7	118:8 127:9
<b>ability</b> 50:5 58:22	<b>addition</b> 142:9	93:23 95:4,10	61:12 76:25 77:2	130:20 143:5
87:15	171:3 175:8	98:13 99:18	119:19 125:5,7	145:21
<b>able</b> 55:14 60:9	<b>additional</b> 95:21	115:18 116:25	126:3,20 129:1,7	<b>anymore</b> 118:9
106:5 107:25	127:1	130:9 145:4	153:1 155:15	<b>anyones</b> 151:6
128:12 135:6	<b>address</b> 108:19	148:14 149:3	<b>anchored</b> 113:14	<b>anytime</b> 137:22
146:23 147:4	<b>addressed</b> 85:25	<b>agreement</b> 14:10	<b>anesthesia</b> 58:20,20	<b>anyway</b> 67:16
148:2 172:25	<b>addresses</b> 102:5	<b>ahead</b> 44:10	58:23 134:8	<b>apart</b> 109:17
174:20	<b>adequate</b> 55:6	<b>al</b> 1:9	166:12	<b>apogee</b> 121:10
<b>absence</b> 69:11 77:1	65:15 74:1	<b>allocate</b> 154:23	<b>anesthetic</b> 79:20	<b>apologize</b> 164:1
122:25 130:12	<b>adequately</b> 85:25	<b>allowed</b> 131:7	81:13	<b>apparent</b> 125:11
<b>absorbable</b> 57:3	<b>adhesion</b> 73:21	<b>allowing</b> 89:22	<b>animal</b> 40:24 85:20	<b>appear</b> 49:8 108:18
100:2,7,17 112:24	<b>adjacent</b> 125:20	<b>alluded</b> 47:8 77:22	97:4 166:16,21	124:22
112:24	136:5 167:10	<b>alteration</b> 115:16	171:2,9	<b>appears</b> 99:8
<b>abstract</b> 29:20	<b>adulteration</b> 111:1	<b>altering</b> 132:21	<b>animals</b> 118:6	108:12 138:11
31:12 39:2 81:16	<b>advance</b> 54:5 144:6	134:17	<b>ann</b> 138:14	<b>appended</b> 5:20
<b>abstracted</b> 33:3,7	<b>advancing</b> 106:10	<b>alternate</b> 104:22	<b>anne</b> 130:4	24:17,18,19,20
<b>abstracts</b> 7:21	<b>advantage</b> 116:24	<b>amendments</b>	<b>annual</b> 110:23	25:4
<b>accepted</b> 103:15	<b>advantages</b> 100:13	110:20	<b>answer</b> 28:17 30:8	<b>applicable</b> 125:2
104:7	100:15	<b>american</b> 16:14	30:24 31:25 32:9	<b>application</b> 98:4
<b>access</b> 119:24	<b>adverse</b> 78:6 90:7	53:20 103:19	32:11 36:16 62:11	<b>applied</b> 57:4 68:5
<b>accident</b> 138:3	90:12,18 110:6	104:3 122:12	71:21 83:19 89:25	<b>applies</b> 125:3
<b>accomplish</b> 43:5	111:15,15 122:8	174:24 175:17	91:24 97:7 129:20	<b>applique</b> 57:4 73:5
50:5,6	135:11 138:11,17	<b>amount</b> 27:1 65:15	157:5 158:6	176:20
<b>accuracy</b> 11:17	139:3,12 148:9	79:21 83:9 88:23	159:24 163:22	<b>apply</b> 46:5 98:13
<b>accurate</b> 9:17	149:17,20 150:7	113:4 134:3	170:23 174:17	174:1
29:18 73:10 97:2	150:12	<b>analysis</b> 147:22,23	176:10,16	<b>appreciable</b> 76:18
133:5 139:15,20	<b>advice</b> 143:15	148:7 149:10	<b>answered</b> 32:8	<b>appreciably</b> 76:14
<b>accustomed</b> 57:16	<b>advised</b> 97:15	154:13,16	38:19 64:22 65:3	162:5,9
<b>acknowledgment</b>	141:13	<b>analyzed</b> 145:3	88:1,17 131:2	<b>approach</b> 30:14
178:1	<b>advocate</b> 150:22	<b>anatomic</b> 48:4 49:1	156:10	47:7 93:9 99:19
<b>acquire</b> 131:11,13	<b>advocates</b> 87:9	49:20 52:5 54:11	<b>answering</b> 158:5	<b>approached</b> 92:25
131:17,18,23	141:8	77:4 104:23	<b>answers</b> 99:15	<b>appropriate</b> 95:6
149:25	<b>affairs</b> 63:19	152:15 155:14	178:3	95:15,19 102:4
<b>acquired</b> 147:3	<b>affect</b> 132:4	<b>anatomical</b> 15:21	<b>antecedent</b> 140:15	<b>approval</b> 64:2,5,10
<b>acquisition</b> 154:9	<b>afternoon</b> 9:7	46:10,14,19 48:13	<b>anterior</b> 15:22 49:5	65:8,16,19 66:1
<b>act</b> 110:22	<b>agency</b> 64:2,16	48:18 49:3 74:9	59:8 71:7 126:4	83:8 110:15
	65:11 98:5	76:10,14,19 104:1	127:12,16,19	<b>approve</b> 65:25

<b>approved</b> 64:6 66:14 79:25,25 80:5,8,17,20,24 86:16 87:16,23 90:7,18 110:16	75:23 81:16 103:16 105:25 106:18,25 107:11 107:18,20,20 108:25 148:21 155:3 170:24	<b>assembly</b> 128:4 <b>assess</b> 32:25 168:11 <b>assessed</b> 168:18 <b>assessing</b> 46:5 <b>assessment</b> 28:24 48:11 67:9,18 127:10 148:17	74:20 84:24 86:25 91:17 93:5 105:16 141:9 160:18 167:18,20,22 168:6 175:2,9 <b>avaulta</b> 12:10,11 12:16	<b>base</b> 75:20 160:24 <b>based</b> 19:21 22:2 34:11,11 44:22 45:8 66:10 74:11 77:1 87:3 113:12 113:20 142:2 144:14 147:23 173:7 174:6,12
<b>approximate</b> 27:12 <b>approximated</b> 104:22 114:23 <b>approximately</b> 9:11 27:2 33:12 36:9 58:17 70:2 156:4 162:2	<b>articles</b> 7:16,23,24 11:13,15,17 14:24 15:4,11,20 16:19 17:11,11,16,23 18:13 19:2,8 29:11 30:3,4,10 30:13,15,19 31:2 32:4,17,18 33:4,7 41:2,7 86:4 103:8 104:8 106:8 107:23 108:3,7 130:3 131:3,11 168:14 170:8,18 170:19,20,23 171:13,14	<b>assigning</b> 45:5 <b>associated</b> 47:4 52:6 73:11 75:4 76:8 110:11 114:3 115:12,13,15 119:13 122:8 130:11,17 134:12 139:16 159:8 161:8 <b>associates</b> 46:4 50:10,20 176:11 <b>association</b> 111:13 <b>attached</b> 5:15 42:14 52:3 178:5 <b>attempt</b> 108:19 <b>attempting</b> 84:20 <b>attending</b> 174:13 <b>attention</b> 143:11 <b>attorney</b> 26:10 165:2 <b>attributed</b> 111:16 <b>august</b> 110:15 <b>austin</b> 1:18 4:8 <b>author</b> 81:19 82:1 106:22,23 129:14 <b>authors</b> 37:19 49:18 81:10 104:16,25 122:20 122:21,21,25 123:17,21,25 124:9 125:4,4 126:3,11 127:21 129:9 131:5 138:11 161:22 168:19,21 <b>autologous</b> 46:18 59:3 <b>available</b> 30:13 56:10 74:12,13,15	<b>average</b> 95:23 96:13 142:3,4 <b>avid</b> 141:8 <b>avoid</b> 55:8 104:17 120:11 141:19 149:18,21,22 150:8,9 158:6 <b>avoided</b> 110:3 <b>avoiding</b> 154:8 <b>aware</b> 56:9,10 67:14 72:12 77:10 94:23 128:11 149:20 168:13 169:8	<b>baseline</b> 106:3 109:4 129:20 131:19 132:9,12 132:14,19 133:3 <b>basically</b> 18:12 100:5 101:3 118:6 148:23 <b>basis</b> 31:7 44:6 53:25 77:19 82:20 89:2 145:4 170:9 <b>bears</b> 43:17 <b>beautifully</b> 135:8 <b>beck</b> 1:16 2:11 <b>beckredde</b> 2:16 <b>becoming</b> 115:14 <b>beg</b> 101:6 107:12 117:7 160:12 171:2 <b>began</b> 58:23 59:7 69:3 106:1 117:10 121:7 <b>beginning</b> 32:16 51:14 98:21 105:14 146:10 164:24 <b>begins</b> 119:24 <b>behave</b> 173:19 <b>behaved</b> 158:21 <b>behaves</b> 66:9 <b>believe</b> 5:20 8:11 10:13,24 11:8 12:9 25:24 29:16 29:18 40:4 41:10 42:25 45:7 46:11 47:24 48:11 49:2 49:18 62:10 70:15 80:19 89:13 90:21 93:10 94:8 102:23
<b>arbitrary</b> 153:7 <b>arbor</b> 138:14 <b>area</b> 28:20 45:13 48:16 50:17 115:13 120:8 125:20 126:9 136:3 159:3 167:11,14,14 172:21 <b>areas</b> 89:17 99:16 138:13 159:2,4 <b>arent</b> 30:11 32:15 78:16 84:23 175:14,15 <b>arm</b> 60:1 <b>arms</b> 52:19 53:4 57:16,21 59:15 62:14 104:17,19 105:7 113:12,16 113:22 114:8,21 119:7,15 135:19 135:25 <b>arrived</b> 9:8 <b>artery</b> 104:4 <b>arthritis</b> 132:13 <b>article</b> 3:14 16:12 29:19 31:11,12,20 32:3 34:15 36:23 37:4 38:6 41:13 43:14 46:3 48:10 49:13 72:23 73:4	<b>articulate</b> 66:20 <b>articulating</b> 78:4 <b>aside</b> 95:23 <b>asked</b> 21:17 24:14 25:8,25 26:12,14 30:25 31:24,24 32:7,10 38:18 64:21 65:2,21 72:18 84:11 87:14 88:1,16,25 96:14 107:16 120:17 121:23 127:10 136:23 144:21 147:2 155:3 156:10 168:4 169:2,23 174:9 176:3 <b>asking</b> 13:6 28:22 29:24 30:7 39:8 49:25 62:4 65:4,8 88:2 95:10 156:18 <b>asks</b> 65:11 <b>aspects</b> 54:14 65:17 67:8 76:4 86:11 89:6 91:18	<b>assembly</b> 128:4 <b>assess</b> 32:25 168:11 <b>assessed</b> 168:18 <b>assessing</b> 46:5 <b>assessment</b> 28:24 48:11 67:9,18 127:10 148:17 <b>assigning</b> 45:5 <b>associated</b> 47:4 52:6 73:11 75:4 76:8 110:11 114:3 115:12,13,15 119:13 122:8 130:11,17 134:12 139:16 159:8 161:8 <b>associates</b> 46:4 50:10,20 176:11 <b>association</b> 111:13 <b>attached</b> 5:15 42:14 52:3 178:5 <b>attempt</b> 108:19 <b>attempting</b> 84:20 <b>attending</b> 174:13 <b>attention</b> 143:11 <b>attorney</b> 26:10 165:2 <b>attributed</b> 111:16 <b>august</b> 110:15 <b>austin</b> 1:18 4:8 <b>author</b> 81:19 82:1 106:22,23 129:14 <b>authors</b> 37:19 49:18 81:10 104:16,25 122:20 122:21,21,25 123:17,21,25 124:9 125:4,4 126:3,11 127:21 129:9 131:5 138:11 161:22 168:19,21 <b>autologous</b> 46:18 59:3 <b>available</b> 30:13 56:10 74:12,13,15	<b>avaulta</b> 12:10,11 12:16 <b>avenue</b> 1:17 <b>average</b> 95:23 96:13 142:3,4 <b>avid</b> 141:8 <b>avoid</b> 55:8 104:17 120:11 141:19 149:18,21,22 150:8,9 158:6 <b>avoided</b> 110:3 <b>avoiding</b> 154:8 <b>aware</b> 56:9,10 67:14 72:12 77:10 94:23 128:11 149:20 168:13 169:8	<b>base</b> 75:20 160:24 <b>based</b> 19:21 22:2 34:11,11 44:22 45:8 66:10 74:11 77:1 87:3 113:12 113:20 142:2 144:14 147:23 173:7 174:6,12 <b>baseline</b> 106:3 109:4 129:20 131:19 132:9,12 132:14,19 133:3 <b>basically</b> 18:12 100:5 101:3 118:6 148:23 <b>basis</b> 31:7 44:6 53:25 77:19 82:20 89:2 145:4 170:9 <b>bears</b> 43:17 <b>beautifully</b> 135:8 <b>beck</b> 1:16 2:11 <b>beckredde</b> 2:16 <b>becoming</b> 115:14 <b>beg</b> 101:6 107:12 117:7 160:12 171:2 <b>began</b> 58:23 59:7 69:3 106:1 117:10 121:7 <b>beginning</b> 32:16 51:14 98:21 105:14 146:10 164:24 <b>begins</b> 119:24 <b>behave</b> 173:19 <b>behaved</b> 158:21 <b>behaves</b> 66:9 <b>believe</b> 5:20 8:11 10:13,24 11:8 12:9 25:24 29:16 29:18 40:4 41:10 42:25 45:7 46:11 47:24 48:11 49:2 49:18 62:10 70:15 80:19 89:13 90:21 93:10 94:8 102:23

Bobby Lewis Shull, M.D.

Page 184

105:13,16 106:17 111:11 117:21 127:11 151:7 167:19 174:5 176:23,25 177:2 <b>belong</b> 45:12,18,22 45:23 46:7 <b>beneficial</b> 47:17 <b>benefit</b> 62:24 75:17 76:12,12,18,23 78:3,4 127:25 141:23 144:25 158:15 <b>benefits</b> 45:24,25 50:6 54:25 55:3 76:24 93:25 127:23 145:3,7 <b>best</b> 30:1 40:11 41:21 47:25 52:16 60:22 80:2 81:23 92:17 93:8 100:4 110:7 124:18 137:11 140:16 141:18 164:18 173:23 176:18 <b>better</b> 27:20 49:8 49:19 57:6 76:13 77:23 78:11 123:23 124:13 125:9 126:5,20 127:13,16,17 133:2,15 135:23 139:5 141:24 142:2,4,7 143:15 146:24,25 147:5 162:6,9 166:11 <b>beyond</b> 28:16 <b>bias</b> 129:22 <b>biased</b> 78:14 <b>bibliography</b> 36:21 37:8 41:2 72:22 72:25 <b>big</b> 62:2 146:10 147:20,20 <b>bigger</b> 61:2 146:11 <b>biggest</b> 146:7,9	<b>bill</b> 14:15 18:7,8 <b>billing</b> 6:17 <b>binary</b> 88:18 <b>binder</b> 8:4,16 15:2 15:7,9,12,13 17:6 17:10 19:2,9 29:13 31:14 102:20,25 103:7 106:19 107:21,24 108:4 <b>biological</b> 46:17 <b>biomaterial</b> 118:2 118:4 <b>biomaterials</b> 63:5,8 118:2 <b>bit</b> 6:23 66:16 <b>bjog</b> 15:23,23 103:13 <b>blabber</b> 157:5 <b>bladder</b> 58:2,11 70:3 79:11 118:13 125:6 146:16 155:9 159:18 <b>bleeding</b> 126:1 <b>blind</b> 59:15,21,25 62:14 119:7 <b>board</b> 79:25 80:6 <b>boards</b> 80:18 <b>bob</b> 3:16 101:14 177:7 <b>bobby</b> 1:10 3:3,12 4:18,24 178:8 179:4 <b>bodies</b> 80:25 115:23 120:1 <b>body</b> 52:22 115:19 115:19 116:1,11 136:19,20 137:2 142:11 167:4 <b>bodys</b> 138:1 <b>bonet</b> 20:11,12 21:11,18 <b>boston</b> 11:8 12:6 <b>bothered</b> 133:17 <b>bothers</b> 150:14 <b>bought</b> 160:9	<b>bowel</b> 3:15 37:13 38:3,7,9,11 58:2 58:11 70:20,21,22 73:21 118:12 146:16 155:5,10 159:18 <b>box</b> 7:24 8:21 14:21 17:17,22 18:2,3,7 19:4,13 23:19 82:13 92:8 <b>bracken</b> 81:22 <b>brand</b> 52:14 <b>break</b> 9:2 34:8 51:4 98:23 164:19 <b>breakdown</b> 42:6 <b>breakfast</b> 9:20 <b>breanne</b> 102:10,12 <b>briefly</b> 9:7 <b>bring</b> 50:25 <b>british</b> 108:25 <b>broad</b> 46:20 <b>brought</b> 5:13 10:6 15:5 <b>brubaker</b> 41:10 <b>bulk</b> 74:2 <b>bunching</b> 162:18 <b>buy</b> 160:12 <b>buys</b> 89:15 <hr/> <b>C</b> <hr/> <b>c</b> 2:1 4:1 <b>cadaver</b> 155:19,20 155:22 <b>cadavers</b> 155:23 <b>calculate</b> 134:10 <b>calculated</b> 148:7 <b>calendar</b> 36:4 <b>caliber</b> 109:22 <b>call</b> 11:16 102:12 148:1 <b>called</b> 59:2,3 75:24 79:18 109:19 118:6 123:9 125:5 129:21 131:25 135:20 147:22 148:7 149:10	166:12 169:12 <b>canal</b> 43:15 49:5,6 58:8,9,10,13,18 70:19 85:12 86:3 86:7 105:6 109:23 115:1,16 118:18 127:15 145:20 159:2,4,20 166:11 <b>candidate</b> 45:4 140:15,16,17 142:3 <b>candidates</b> 141:21 164:17 <b>cant</b> 13:18 38:20 39:15 61:14,25 70:17 102:21 107:8 121:21 132:2,15 135:12 149:22 153:6 154:17,17 156:19 156:20 <b>capable</b> 87:7 132:17 134:1 142:5 <b>care</b> 42:25 43:9 59:22 62:5,18 150:3 <b>cared</b> 144:17 <b>carey</b> 105:23,25 106:21 109:1 128:21 <b>careys</b> 108:18 161:20 <b>caring</b> 46:8 <b>carol</b> 1:6 4:8 <b>cascade</b> 116:16 132:4,8 <b>case</b> 1:7 27:8 30:21 34:13,18 36:20,25 37:13,19,22 38:1 41:8 60:2 66:3,8 67:24 68:7 72:8 83:25 85:8 89:15 100:23 104:4 124:11 132:18 134:13,23 135:7	159:19 <b>cases</b> 24:15,16 26:20 27:5 56:1 56:20 <b>casespecific</b> 25:4 26:25 27:12,23 <b>categories</b> 58:7 114:5 131:12 176:16 <b>category</b> 115:9 131:12 143:4 <b>caught</b> 131:24 <b>cause</b> 114:12 115:20 137:4 <b>causing</b> 115:14 146:24 <b>caveat</b> 139:7 <b>cavity</b> 86:7 <b>cds</b> 92:2 <b>center</b> 80:21 <b>centimeters</b> 42:11 <b>central</b> 105:7 <b>century</b> 59:4 <b>certain</b> 12:5 25:17 36:17 40:3 64:12 69:25 74:19 96:24 98:1 121:1,7 130:13 134:3,11 142:6 148:24 159:10 164:13 169:25 173:14 175:15 <b>certainly</b> 8:13 34:25 47:17 95:18 140:21 170:10 <b>certificate</b> 179:1 <b>certified</b> 1:21 179:3 <b>certify</b> 178:3 179:4 179:9 <b>chain</b> 92:15 <b>challenging</b> 77:18 156:1 <b>chance</b> 51:5 <b>change</b> 133:25 134:21 167:10 180:3
---	--	---	--	---

Bobby Lewis Shull, M.D.

Page 185

<b>changed</b> 6:8 151:19	109:13	171:14	123:4	<b>complications</b>
<b>changes</b> 114:12	<b>clearance</b> 64:11,15	<b>com</b> 2:8,16	<b>compared</b> 69:8	33:13,17 34:2
178:4	66:12 83:8 112:11	<b>come</b> 28:8 29:13	106:1 112:7 115:4	35:3,13,20 39:5,5
<b>changing</b> 133:22	<b>cleared</b> 64:13	49:3 65:14 70:18	<b>comparing</b> 78:20	55:9,10 73:10,21
<b>characteristic</b>	109:19	133:12,17 141:9	161:21	86:21 87:10
68:14	<b>clearly</b> 31:25 74:19	143:25 151:16,18	<b>comparison</b> 43:21	109:10 113:25
<b>characteristics</b>	136:17	166:5 170:11	106:24 113:25	114:3 115:8
136:9 138:7 150:3	<b>cleveland</b> 130:5	<b>comes</b> 10:13 28:4	115:3	130:24 133:19
<b>characterization</b>	<b>clinic</b> 40:23 130:5	60:25	<b>compartment</b> 49:4	139:16 150:17
171:16	<b>clinical</b> 21:13,21,24	<b>comfort</b> 150:15	59:8 125:13,16,18	152:8,11 154:8,8
<b>characterized</b>	40:20,25 63:7	<b>comfortable</b> 9:14	126:4 127:12,14	154:21 156:5
13:25	67:7,9,11,18,23	142:1 158:4	127:17,19	159:10,13 165:14
<b>charleston</b> 1:1 2:6	69:7 78:24,25	<b>coming</b> 143:14	<b>compartments</b>	169:3,5,9 173:25
4:10	79:7 82:24 95:22	<b>comment</b> 41:25	125:6	<b>compound</b> 33:24
<b>check</b> 3:13,17 6:15	96:17 97:6 103:17	44:18,19 86:18	<b>competence</b> 89:21	34:5
10:9,17,17 101:24	103:21 107:12	87:9 124:5 157:2	<b>competent</b> 89:23	<b>comprehensive</b>
<b>chemical</b> 112:25	120:12 122:10	<b>commented</b> 42:19	<b>complain</b> 140:7	140:8
170:5	135:14,15 138:10	42:22 164:12	<b>complaining</b> 139:6	<b>conceived</b> 76:7
<b>child</b> 145:21	142:15 147:13	<b>commenting</b>	<b>complaint</b> 52:20	<b>concept</b> 52:19 53:3
<b>choice</b> 47:12,13	151:22 152:4	140:12	71:7 109:12,14	53:6,20 59:5 77:3
<b>choose</b> 47:9 71:2	158:21 159:11,14	<b>comments</b> 95:2	139:18 142:18	77:24,25 93:8,10
<b>chooses</b> 59:20,22	159:15,15 160:21	<b>commerce</b> 110:19	149:25	93:23 95:11
59:25	170:6 171:22	<b>commercial</b> 53:14	<b>complaints</b> 34:19	105:22 114:15
<b>chose</b> 84:25 105:3	172:1,17,19,22	91:13 147:16	34:20 85:22	161:9
<b>chosen</b> 43:6,10	<b>clinically</b> 21:16	152:6	109:15 111:2,4	<b>concepts</b> 32:22
49:25 50:8	67:24 71:16 125:2	<b>commercially</b> 93:4	113:7,8 114:8,21	171:16
<b>chris</b> 37:6	<b>clinician</b> 170:3	<b>commission</b> 178:16	129:11,12,17	<b>conceptually</b> 78:1
<b>chronic</b> 136:11,12	<b>clinicians</b> 54:13	<b>commit</b> 19:6	130:6 131:9,12,15	<b>concern</b> 124:6
164:6,10	140:20 159:16	<b>commitment</b> 134:4	131:17,18,23	147:12
<b>chung</b> 37:6	<b>close</b> 133:5	<b>common</b> 58:6	133:18 135:9	<b>concerns</b> 14:7
<b>cincinnati</b> 138:14	<b>closed</b> 57:8	91:20,23 164:17	140:4 141:5 153:4	54:13,14 70:19
143:7	<b>closer</b> 27:18	<b>companies</b> 65:6,7	154:9 159:21	73:18
<b>circumstance</b> 50:2	<b>club</b> 15:1	84:9,16,20 91:14	161:11	<b>concluded</b> 177:9
54:22 68:4 77:23	<b>clues</b> 135:14,15	154:15 174:15	<b>complement</b> 47:16	<b>concludes</b> 98:16
<b>circumstances</b>	<b>collagen</b> 16:14	175:1	<b>complete</b> 24:6 25:6	177:6
46:25 48:23 55:12	115:21 171:1,8	<b>company</b> 53:11	73:9 139:15	<b>conclusion</b> 73:8
78:21 96:24	<b>colleagues</b> 40:6	63:1 64:10 65:13	<b>completely</b> 116:8	170:11
115:25 140:1	76:3 169:3,18	84:25 86:1,14	<b>complex</b> 77:8,9	<b>conclusions</b> 30:15
150:16	176:4,7,13,14	87:22,24 88:3,5	135:17 146:15	69:15 161:25
<b>cite</b> 48:3	<b>collect</b> 75:14	91:23 92:25 93:19	<b>complexity</b> 154:19	168:19
<b>cited</b> 11:17 48:9	139:25	97:15 98:6 118:5	<b>compliance</b> 58:1	<b>conditions</b> 63:10
170:8	<b>collected</b> 52:5	<b>comparable</b> 128:24	118:12	<b>conference</b> 169:12
<b>clarification</b> 65:11	130:1	129:1,3 152:13	<b>complication</b> 87:12	<b>configuration</b>
<b>class</b> 110:17	<b>collecting</b> 55:22	<b>comparator</b> 123:1	114:2 115:4	114:12
<b>clean</b> 85:14,15 86:2	<b>college</b> 175:17	<b>compare</b> 78:12	133:12 141:17,18	<b>confirm</b> 9:16 10:5
<b>clear</b> 74:6 78:3	<b>colonization</b>	99:9 111:19 113:6	141:19	11:17 81:24 155:4

Bobby Lewis Shull, M.D.

Page 186

<b>confirmation</b> 42:9	46:20 130:7	149:22 160:9,18	141:14 152:14	<b>debate</b> 47:21,22
<b>confirmed</b> 42:13	146:24	169:22 173:10	153:19	<b>december</b> 103:20
<b>confused</b> 121:10	<b>continue</b> 84:17	178:3	<b>critical</b> 49:23 50:1	103:25
<b>confusion</b> 48:16	<b>continuing</b> 133:7	<b>corrected</b> 5:22	<b>critically</b> 168:10,18	<b>decide</b> 121:14
<b>congress</b> 1:17	<b>contract</b> 85:19	124:19	<b>criticism</b> 82:2	152:9
<b>conjunction</b> 111:16	<b>contraction</b> 115:14	<b>corrections</b> 11:12	<b>criticizes</b> 78:24	<b>decision</b> 30:20 50:2
<b>connective</b> 53:4	153:4 159:18	178:4	<b>critique</b> 79:1	64:17 84:9,10
57:17 60:4 146:18	171:15	<b>correlate</b> 173:1	<b>csr</b> 1:21	151:6 166:15
<b>conscious</b> 151:5	<b>contracts</b> 153:5	<b>correspondence</b>	<b>cure</b> 68:18,19	<b>decisions</b> 65:7
<b>consensus</b> 45:21	160:17	17:23 98:7	69:16,23,25 70:6	172:6
46:12 47:19 49:3	<b>contracture</b> 115:21	<b>correspondences</b>	<b>cured</b> 69:23	<b>defect</b> 162:3
65:15 69:19	<b>contraindication</b>	8:1	<b>curious</b> 71:9	<b>defective</b> 172:16
141:10	141:6	<b>cosmetic</b> 110:22	<b>current</b> 5:24 26:18	<b>defects</b> 16:13 171:1
<b>consent</b> 55:19	<b>contraindications</b>	<b>cossan</b> 53:18,19	167:13	<b>defendant</b> 1:10
172:12	140:19	<b>cost</b> 127:24 134:12	<b>currently</b> 83:13	<b>defendants</b> 2:17
<b>consequence</b> 151:8	<b>contribution</b> 155:7	<b>coughing</b> 70:3	127:2 137:17	<b>deferens</b> 146:3
166:14 172:20	<b>control</b> 60:22,24	<b>couldnt</b> 121:12	141:7 153:21	<b>defined</b> 48:15 55:6
<b>consequences</b>	61:1,10 70:3	<b>counsel</b> 4:11 15:18	176:21	55:12,13 79:14
171:22 172:23	124:7	17:12 18:15 19:16	<b>curriculum</b> 3:12	105:4 128:10
<b>consider</b> 63:4,15,18	<b>controls</b> 110:21	20:8,9 22:16,17	5:19 24:24 101:11	<b>defines</b> 124:25
63:21,23 64:19	<b>conversant</b> 64:23	23:5,20 24:8	<b>curt</b> 2:12 4:15,25	<b>defining</b> 16:4
65:1 96:15 97:8	64:25	29:14,21 30:5	<b>curve</b> 124:2,4	<b>deformation</b>
117:3,13 133:22	<b>conversation</b>	31:3 32:6 72:7	<b>curved</b> 61:3	162:19
141:13 167:12	141:25	74:11 82:15 92:8	<b>customers</b> 174:20	<b>degradation</b> 42:6
<b>considerably</b>	<b>converse</b> 77:13	108:5,8,11 142:19	<b>cut</b> 135:24 137:25	42:20,22 67:3
113:10 146:15	<b>convinced</b> 50:5	143:13 145:12,15	157:6,7	70:12 71:19,23
<b>considered</b> 68:17	<b>copied</b> 107:23	179:10	<b>cv</b> 5:25 81:25	<b>degree</b> 45:6 54:6
169:24	<b>copies</b> 32:14	<b>counseled</b> 70:2	<b>cwebb</b> 2:16	58:10 136:7 142:6
<b>considering</b> 63:20	<b>copy</b> 6:5 94:17	<b>counseling</b> 54:23		163:10 164:14
<b>consisting</b> 52:3	101:7,8	86:12 89:6	<b>D</b>	<b>degrees</b> 164:13
<b>construct</b> 28:21	<b>correct</b> 5:1 6:1,18	<b>count</b> 19:10	<b>d</b> 1:10 3:1,3,12,16	<b>delay</b> 70:22
<b>consulted</b> 144:5	7:13 8:19 12:16	<b>countries</b> 80:25	4:1 178:8 179:5	<b>delivery</b> 100:4
<b>contact</b> 102:4	13:1,15 14:3	<b>country</b> 80:22	<b>data</b> 55:22 162:1	<b>demoed</b> 91:5
<b>contacted</b> 25:20	16:21 17:14,25	<b>couple</b> 32:14	<b>database</b> 90:10,18	<b>demonstrate</b>
26:4,18	18:10 21:14,19	<b>course</b> 93:6	<b>date</b> 4:6 25:23	151:25 161:23
<b>contain</b> 17:18	22:5 25:25 27:5	<b>court</b> 1:1 4:10,16	35:17 39:15,18	<b>demonstrated</b> 91:9
<b>contained</b> 172:4,10	28:3 29:16,25	6:9 94:25	110:20 178:8	<b>demonstrating</b>
<b>containing</b> 59:15	33:14 37:21 38:11	<b>cover</b> 20:16 22:21	<b>dated</b> 10:18 15:24	128:2 147:14
62:13 118:25	38:12 45:10 52:23	23:11 103:3	23:2,21 101:25	152:4
119:6	59:18 83:17 93:15	<b>covered</b> 9:15	103:14 110:15	<b>demonstration</b>
<b>contaminated</b>	93:21 96:25 99:2	<b>create</b> 70:22 115:24	<b>day</b> 155:11 165:6	175:12,15
85:14,16 86:2	99:6 100:9 101:15	153:6	169:15 178:14	<b>demonstrations</b>
159:5	102:15 108:17	<b>created</b> 111:9	179:14	175:5
<b>content</b> 7:8	112:3 116:9 117:6	<b>creating</b> 150:24	<b>deal</b> 137:12	<b>deny</b> 88:14
<b>context</b> 20:23 22:19	117:25 118:16	<b>creation</b> 109:21	<b>dealing</b> 130:13	<b>department</b> 40:2
23:8,17 24:3	119:12 139:19	<b>criteria</b> 124:25	174:14	40:12 110:14



125:8 169:10 176:19 <b>departure</b> 56:15,18 57:10 62:2 116:21 116:22 <b>dependent</b> 60:14 60:17 <b>depending</b> 14:5 56:4 61:8 70:5 134:1 148:18 152:7,25 154:12 175:4 <b>depends</b> 50:23 90:21 124:24 <b>deploy</b> 52:18 57:9 <b>deployed</b> 53:21 <b>deploying</b> 53:4 54:9 57:16 <b>deployment</b> 60:1 <b>deponent</b> 4:11 178:1 <b>deposed</b> 25:9,11,12 120:17 <b>deposition</b> 1:9 3:2 3:11 4:7 5:3,9,15 6:1,12 7:6,11 9:5 9:8,21 12:25 15:3 20:6,7,11,23,25 21:2,10,17,25 22:7,9,10,11,12 22:18,24 23:1,4,7 23:13,16,21,23 24:2,7 26:8 28:1 98:17 115:21 171:9 177:7,9 179:5,7 <b>depositions</b> 13:8,11 13:16 20:18,20 25:3 28:1 45:8 94:5 98:13 <b>dermal</b> 16:14 171:1 <b>describe</b> 48:23 123:14 131:7 132:2 147:13,19 <b>described</b> 58:17 133:20 134:23	<b>describing</b> 173:24 <b>description</b> 42:12 66:6 <b>descriptions</b> 14:7 <b>design</b> 79:23 82:3,9 82:16,22 96:16 97:16 158:10 161:9 <b>designed</b> 75:14 82:5 123:11 167:6 <b>desirable</b> 46:15 104:13 119:20 <b>desired</b> 105:11 <b>detail</b> 75:1 <b>detailed</b> 95:1 <b>details</b> 99:11 <b>deterioration</b> 69:25 <b>determine</b> 30:19 106:4 129:13 148:19 <b>determined</b> 110:17 <b>determines</b> 147:23 <b>develop</b> 33:2 53:20 54:19 93:10 131:8 <b>developed</b> 62:25 63:1 72:23 82:5 105:22 106:7 112:12,14 120:4 <b>developing</b> 98:3 100:22 <b>development</b> 82:4 82:9,16,22 97:14 158:10 <b>deviate</b> 61:9 <b>deviation</b> 54:19 57:15,20 <b>device</b> 59:14 62:13 62:25 64:4,13,13 64:15 66:1,13 79:8 82:6 83:2,15 83:21 86:16 87:23 90:19,22 93:24 94:1 95:7,8,15,16 96:21,22,23 97:6 103:13,19,23 104:2,13 105:9,23	106:6,10,15 109:8 109:14,17,18,19 110:9,10,17,20 111:5,6,9,10,12 111:17 113:18 116:19 118:25 119:6,10 124:8,12 128:2,3,13,18 137:20 145:1,10 147:14 152:5 158:15 161:9,10 173:12 <b>devices</b> 51:18,24 56:15 58:5 63:13 63:20 73:11 75:18 82:4,10,17,23 90:8 91:2 110:18 110:24 111:24 112:2,3,7 139:17 169:19 172:16 173:4,18 174:5 176:5,8 <b>diabetes</b> 141:4 <b>diagnosed</b> 33:12 156:4 <b>diagnosis</b> 71:20 <b>diagnostic</b> 146:8 <b>didn't</b> 19:6,10 27:25 32:11 38:25 39:13 41:9 59:5 62:20 66:17 69:18 70:25 76:20 79:23 82:11 84:24 90:15 94:21 118:21 121:18 123:2,6 126:18 127:7 129:19 130:19 160:25 162:5,7 164:2 174:11 <b>died</b> 132:12 149:19 <b>differ</b> 99:18 <b>difference</b> 99:22 100:3 113:15 114:2 129:19 135:17 137:15 138:23 165:23,24	<b>differences</b> 118:19 159:6 <b>different</b> 12:2 17:24 30:4 31:16 36:10 45:12 47:18 57:25 58:19 61:15 63:25 76:14 77:5 83:8 84:17 100:1 108:1 109:25 110:12 112:9 113:11,21 114:3 118:4,5,10 119:4 120:9 125:12 130:21 135:1 143:2 150:16,17 161:14,17 166:23 167:1,3,8 175:19 <b>differently</b> 13:25 25:7 62:22 135:1 <b>difficult</b> 77:15,17 114:14 136:2 155:24 <b>difficulty</b> 136:4,7 <b>dilemma</b> 60:12 151:4 <b>diligence</b> 82:3,21 158:10 <b>dimensions</b> 42:10 68:11 <b>dimock</b> 1:6 4:8 <b>direct</b> 160:14 <b>directly</b> 43:18 111:17 156:8 <b>disadvantages</b> 100:13 <b>disappointed</b> 132:16 <b>disapprove</b> 65:25 <b>disc</b> 51:14 98:21 164:24 <b>disclose</b> 75:17 144:24 <b>disclosed</b> 74:24 <b>disclosure</b> 55:1 <b>discuss</b> 10:1 39:17 111:3 169:15	174:20 <b>discussed</b> 9:13,15 26:3 94:7 98:8 102:9 118:21 120:1 128:14 173:4 <b>discusses</b> 171:21 <b>discussing</b> 91:22 93:18,19 122:20 165:10 <b>discussion</b> 21:24 100:6 122:19 175:12 <b>discussions</b> 168:23 <b>diseases</b> 135:3 <b>disorders</b> 40:2 <b>displaced</b> 105:8 <b>disputing</b> 127:12 <b>dissected</b> 119:23 <b>dissection</b> 119:17 119:20 136:4 <b>dissolve</b> 166:1,15 <b>dissolved</b> 113:3 <b>distensibility</b> 58:1 118:12,23 <b>distensible</b> 70:21 <b>distortion</b> 115:1 <b>distribute</b> 102:3 <b>district</b> 1:1,1,6 4:9 4:10 <b>diverge</b> 46:22 <b>doctor</b> 26:21 50:3 59:1,7 133:17 138:18,18,22 140:2 143:14 144:17 150:15 156:18 160:15 <b>doctors</b> 47:21 49:2 70:7 73:9 80:16 138:23 139:1,14 143:18 150:18,21 153:8 167:16 174:21 <b>document</b> 6:15 16:16 19:23 44:21 66:15 74:25 94:11
--	---	---	---	--

Bobby Lewis Shull, M.D.

Page 188

94:21 167:17 <b>documentation</b> 83:9 84:18 <b>documented</b> 100:16 <b>documents</b> 5:14 7:25 8:8,14,21,24 14:6,21,22 17:19 18:14 19:4,14,14 19:15,20,21,21 20:3 24:12 44:20 64:12 82:9,13,16 92:5,6,7,12,12,19 93:12,20 94:5,6 94:10 98:7 101:18 102:8,18,19 103:5 108:13 110:13 154:2 160:25 161:1,4,4 163:18 174:13,18 <b>doesnt</b> 24:23 45:2 46:12 68:8 74:25 77:4 89:12 97:3 113:21 114:22 116:3 120:11 129:19 137:14 138:22 139:9 145:24 146:6 153:25 163:2,6 <b>doing</b> 11:23 14:13 21:17 24:9 60:16 71:16,17 78:13 87:7 93:5 96:13 104:14 108:24 109:3 117:12 127:2 132:17 134:2 155:18,22 176:17 <b>dollars</b> 27:9,10 <b>domestic</b> 174:24 <b>dont</b> 6:10 7:5 11:7 11:9 12:4,7 19:23 20:14 25:23 27:1 27:3,3 28:8 31:16 31:25 34:13 35:17 36:16,17,18 39:17	43:14 44:11 45:6 47:19 48:17 55:20 60:15,20 61:10 62:9,10 64:1,23 65:4 66:20 67:15 70:16 71:7 72:8 72:20,25 73:6,25 75:7,9,11,13 76:22 78:17 81:2 81:20 83:19 87:19 88:9,10 89:10,10 89:13,18,25 90:11 90:25 93:2,8 94:8 94:8,13 97:24 98:2 100:15,22 102:23 104:25 105:2 110:6,9 111:10,11 113:9 117:20,20 118:8 119:11 121:4,11 121:15,16 122:1 124:6 126:13 127:9,11 128:8,13 128:14 130:20 131:14,18 133:4 135:7 136:6,14,17 136:18 137:11 139:6,8,8,9 140:25 142:8,10 142:18 143:5 144:6,12 145:13 146:2,3,25 147:10 151:5,7,7 153:4 156:24 157:1 158:20 160:3,14 162:22,24 164:9 165:21 166:15,22 167:21 173:14 176:18,19,21,24 177:1,2 <b>doubt</b> 82:11 155:12 <b>downward</b> 131:25 132:8 133:16 <b>dr</b> 3:13,17 4:11,25 5:13 7:8 8:8 9:6,9 12:23 17:5 26:3,6	26:9,18 28:22 31:18 37:6 40:5 41:10 46:4 49:13 53:18,18 59:9 72:23 73:3 75:24 76:3 78:9,10 81:22 92:24 98:17 98:23 104:10 105:23,24,25 106:21,22 108:18 109:1 117:7,19 122:13 123:7,8 128:21 130:4 131:5 165:1 168:3 177:7 <b>draft</b> 10:20,22 11:3 11:4,12,18 18:19 28:9 102:10,11 <b>drafted</b> 10:25 <b>drafting</b> 28:13 <b>drive</b> 8:8,9 103:2 <b>drug</b> 79:8 110:22 <b>duces</b> 5:14,18 24:15 <b>due</b> 11:20,21 38:3 82:3,21 158:10 <b>duly</b> 4:19 179:6 <b>duplicated</b> 102:24 <b>durability</b> 149:13 <b>durable</b> 149:1 <b>duration</b> 139:21 <b>dynamic</b> 134:21 <b>dyspareunia</b> 129:11 <hr/> <b>E</b> <hr/> <b>e</b> 2:1,1 3:1,9 4:1,1 77:5 180:1 <b>earlier</b> 47:8 56:1 69:21 73:3 85:10 103:3 117:10 118:3,21 120:1,15 123:9,22 127:10 133:20 136:23 140:5 155:4 160:5 <b>early</b> 35:10,11	56:22 59:4 74:6,8 87:4 91:19 118:7 <b>earned</b> 26:17 <b>earthly</b> 143:12 <b>easier</b> 77:12 <b>easiest</b> 145:19,23 <b>easy</b> 119:25 129:12 <b>editorial</b> 41:8,10 <b>educate</b> 34:22 <b>educated</b> 86:20 <b>education</b> 16:20 39:16 40:7 <b>educational</b> 137:13 <b>effect</b> 50:8 79:3 80:2 110:6 <b>effective</b> 47:2 83:3 83:16,22,22 84:3 84:13 128:16 <b>effectively</b> 83:4 150:19 155:25 158:5 <b>effects</b> 47:4 74:8 90:12 159:18 <b>efficacy</b> 79:4 84:19 128:3,8 139:16 160:22 161:6 <b>efficiency</b> 79:3 <b>efficient</b> 83:3 <b>effort</b> 79:11 109:8 <b>eight</b> 11:19 <b>either</b> 36:14 37:22 39:5,19,24 41:11 44:23 47:15 49:5 54:16 56:24 58:22 60:21 65:11,25 79:14 86:8 93:14 99:17 100:13 104:20 105:8 112:11 120:15 124:7 127:19 129:6 135:20 138:4,21 140:1 144:16 155:10 165:22 166:17 <b>elasticity</b> 67:6,16 <b>eliminate</b> 109:10	114:6,16,22 152:18,21 <b>eliminated</b> 151:11 <b>elimination</b> 141:21 <b>elses</b> 155:6 <b>email</b> 17:23 92:14 <b>emails</b> 44:20 <b>employed</b> 179:10 <b>emptying</b> 70:22 <b>enactment</b> 110:19 <b>encompass</b> 95:17 <b>endpoint</b> 48:14 49:7 126:4 <b>entail</b> 18:12 19:2 <b>entails</b> 22:8 <b>enter</b> 160:16 <b>entire</b> 22:18 23:7 23:16 24:2 94:21 150:22 <b>entirely</b> 41:22 100:1 120:5 160:19 <b>entitled</b> 3:14 106:13 <b>entrapping</b> 165:18 <b>entry</b> 10:20,21 18:18 19:1 137:23 <b>environment</b> 57:25 118:10 <b>equal</b> 78:15,16,16 125:9 126:8 133:3 146:9 <b>equally</b> 87:7 <b>equivalent</b> 66:13 110:18 <b>erode</b> 136:16 <b>erosion</b> 37:5 59:12 73:19 126:1 129:5 159:17 <b>errata</b> 178:5 <b>error</b> 155:12 156:12 <b>errors</b> 156:13 <b>especially</b> 39:9 167:6 <b>esq</b> 2:4,12
--	---	--	--	--

<b>essential</b> 58:2 118:12	69:13	112:22 117:11	<b>expense</b> 134:9 154:19	<b>expressed</b> 51:17 88:11 111:20
<b>estimate</b> 19:11 27:20	<b>evidence</b> 41:25 42:4 51:22,25	151:18	<b>experience</b> 35:11 45:17 50:4 63:12	118:15
<b>et</b> 1:9	52:2 85:17 111:23	<b>exceptional</b> 42:18 144:20	76:16 77:8 86:24	<b>extended</b> 134:5
<b>ethibond</b> 166:2	<b>evident</b> 73:20	<b>exceptions</b> 154:24 166:10	95:5,6,13,14,18	<b>extension</b> 126:6
<b>ethicon</b> 1:3,9 2:17 4:9,15 8:14,24	<b>evolution</b> 49:21,22 104:15	<b>excerpts</b> 94:19	95:22 96:16 109:4	<b>extensive</b> 86:24
13:20 14:21 17:19	<b>exact</b> 7:5 11:7,9	<b>excess</b> 116:4	169:2 173:9,15	<b>extent</b> 75:6
19:4,13 24:11	25:23 27:1 35:17	<b>excessively</b> 141:3	<b>experienced</b> 86:20	<b>external</b> 53:5
44:1,7,8,13,15	36:16 39:18 112:1	<b>exchange</b> 98:5	96:11	<b>externally</b> 93:14
44:19,21 50:22	116:19 133:4	<b>excision</b> 129:6	<b>experimental</b> 63:10	121:13
65:13 73:8 74:14	<b>exactly</b> 12:8 27:4	<b>excluded</b> 94:25	<b>expert</b> 3:16 6:7	<b>extra</b> 127:6
75:9,16 77:19	42:3 61:21 62:20	<b>excuse</b> 14:5 18:21	25:5,13,15,21	<b>extremely</b> 155:24
79:2 82:3,8,21	107:15 121:5,11	35:10 40:1 45:3	28:7,11 29:2,3,6,9	<b>eye</b> 116:2
85:1 86:9,14,19	140:3 163:3,7	46:3 57:5 58:6	29:12 33:2,10	
87:2,15,25 88:9	<b>exaggerates</b> 61:5	63:6 65:23 67:5	35:8 63:4,8,15,18	<b>F</b>
88:12,14 89:7,11	<b>exam</b> 173:1,1	68:2,24 72:20,21	64:20,24 65:1,5	<b>fact</b> 36:19 38:1,23
89:12,20 90:1	<b>examination</b> 3:2	75:21 79:9 82:7	65:22 92:4 94:7	52:19 60:13 61:14
91:2 92:5,6,19,23	4:20 34:12 168:1	83:7 89:10 92:10	94:11 97:9,13,14	67:25 77:17 80:22
93:9,14 94:6 98:8	176:1	92:17 93:22 94:8	98:25 99:4,9,10	81:18 85:19 93:2
102:19 108:13	<b>examinations</b>	95:1 105:5 108:23	101:3,8,14 120:16	98:1 106:8 107:9
139:14 144:24	42:18	111:8 112:9,10	136:23,24 169:24	110:13 116:7
151:22 158:9,17	<b>examine</b> 71:10	113:22 118:24	<b>expertise</b> 89:20	122:16 124:3
158:23 159:9,22	<b>examined</b> 33:12	119:17 128:7	167:14 172:25	130:2 143:3 144:5
160:5,21 167:16	70:23 156:4	129:10 166:25	<b>experts</b> 143:11	147:3
174:10,11,13	<b>example</b> 14:1 19:24	<b>executed</b> 152:17	<b>expires</b> 178:16	<b>factors</b> 122:18
<b>ethicons</b> 161:5	20:10,25 32:16,22	<b>execution</b> 60:17,18	<b>explain</b> 10:21	139:22
174:1,9	41:23 43:22 44:18	<b>exercise</b> 82:3,21	156:11	<b>failed</b> 75:16 79:2
<b>evaluate</b> 54:4 90:3	47:10 48:20 59:6	158:10	<b>explained</b> 94:7	144:24 153:23
123:11 160:22	60:19,24 66:5,9	<b>exhibit</b> 4:2 5:8,23	<b>explant</b> 72:5 77:17	161:22 163:21
161:6	70:18 74:7,22,24	5:25 6:12,13 10:9	120:14 144:1,2	<b>failing</b> 148:4
<b>evaluated</b> 48:17	75:23 76:20 85:8	10:16 37:11,12	171:17 173:16	<b>fails</b> 147:25 148:1,5
69:22 171:6	91:20 92:14 94:14	100:11 101:3,13	<b>explantation</b> 41:17	<b>failure</b> 46:14 76:10
<b>evaluating</b> 63:8	94:15 116:12	101:22,23	169:17	76:14 86:22 148:1
173:16	126:24,25 133:24	<b>exhibits</b> 91:13,14	<b>explanted</b> 41:19	148:1,3 152:15
<b>evaluation</b> 42:17	137:4 140:21	174:25	166:24 167:4	<b>failures</b> 152:16,19
59:10 71:3 72:3	145:17 147:24	<b>expect</b> 48:18 56:13	<b>exposed</b> 42:1	<b>fair</b> 6:21 19:17
144:3 159:16	148:12,22 155:3	78:25 132:15	114:11 166:2,7	28:24 29:8 33:1
<b>event</b> 90:7,18 135:5	160:13 162:25	140:3 142:5,17	<b>exposure</b> 59:13	45:14 99:12,19
142:12 150:7	165:16 169:17	149:4,5 166:23,25	73:19 74:22 76:11	101:20
<b>events</b> 78:6 111:15	171:11 172:9	167:2 172:8	76:21 86:23	<b>fairly</b> 48:15
112:19 116:16	175:18	<b>expectation</b> 146:20	114:23 126:16	<b>fall</b> 47:17 115:9
122:8 132:4	<b>examples</b> 92:5	<b>expectations</b>	127:18,20 159:19	131:12 143:4
138:12 149:17,20	171:20	122:23 145:17	169:14 172:21,23	<b>familiar</b> 7:7 15:14
<b>everybody</b> 50:1	<b>exams</b> 48:22	<b>expected</b> 18:23	<b>exposures</b> 115:13	30:8 64:9 67:17
	<b>exception</b> 67:14	28:25 166:4	123:18	97:18 173:20
				174:6,8

<b>familiarity</b> 170:3	<b>filed</b> 5:18 6:9	56:11 70:10 71:12	136:22 137:21	<b>fully</b> 76:23
<b>familiarized</b> 11:2	<b>fill</b> 105:6	139:23 148:23	140:11 143:20	<b>function</b> 58:2,11
<b>family</b> 132:5,11	<b>final</b> 11:18 16:12	153:15	144:11 147:17	69:24 70:20 74:8
<b>far</b> 14:12 53:11	23:19 102:11,12	<b>following</b> 69:9	162:23 166:18	118:13 132:13
115:9 122:5	<b>finalize</b> 18:15	79:12 103:21	169:21 171:23	149:6 159:19
<b>fascia</b> 59:2	<b>financially</b> 179:11	130:10 154:24	172:18 173:22	<b>functional</b> 15:21
<b>fashion</b> 10:4 52:4	<b>find</b> 31:1,11 53:7	<b>follows</b> 4:19	174:2,16 176:9	<b>further</b> 84:19
78:14	74:2 107:5,9	<b>followup</b> 76:1	178:4	175:21 179:9
<b>fast</b> 171:7	124:16 125:4	92:14 122:11	<b>formal</b> 33:16 34:2	<b>future</b> 135:6
<b>favorable</b> 54:16	126:11,24 130:25	123:12 126:6	34:11	142:13
168:19	153:11	138:10 139:21	<b>format</b> 9:13 11:2	
<b>fda</b> 34:20 35:4	<b>findings</b> 171:18	141:15 154:11	18:20 28:10,23	<b>G</b>
63:19 65:18,22,25	<b>fine</b> 98:14 99:20	168:25 175:23	<b>formation</b> 68:13	<b>g</b> 4:1
66:18 80:8,13	158:5	<b>food</b> 110:22,22	138:2	<b>game</b> 157:16
83:1,14,20 84:1,6	<b>finish</b> 102:9 151:25	<b>footnotes</b> 171:11	<b>formed</b> 137:24	<b>general</b> 6:4,18 7:7
84:10,12,16,24	<b>firm</b> 14:11	<b>force</b> 91:15	<b>forth</b> 179:6	7:12 8:2,3 9:16
86:16 87:17 90:6	<b>firms</b> 14:12	<b>foregoing</b> 178:3	<b>forward</b> 72:7	10:19,25 11:5,14
90:11,17 110:14	<b>first</b> 4:19 7:10 9:2	<b>foreign</b> 115:19,23	<b>forwarded</b> 19:15	11:23 12:1,6,13
<b>feasibility</b> 54:8	10:20,21 18:18	120:1 136:19,20	<b>found</b> 23:19 29:20	12:15,20,21 13:6
<b>february</b> 10:18	23:10 25:20 26:18	137:2 142:11	31:16 52:2 72:13	13:19 14:16 15:4
101:25	35:12,16 51:21	<b>foreseeable</b> 142:13	108:9 153:13	17:13 18:9,14,16
<b>federal</b> 94:25	70:1 103:11 106:9	<b>forget</b> 44:9,12	168:22	18:19 19:17 24:9
110:22	106:16,17,19	<b>forgive</b> 12:7	<b>four</b> 20:5 23:12	24:19,24 25:5
<b>fee</b> 11:20	107:20 109:7	<b>forgot</b> 107:15	40:1	26:13 27:22 29:23
<b>feedback</b> 90:3	117:11 119:25	<b>form</b> 13:5 14:23	<b>france</b> 53:18 80:19	31:10,13,21 32:4
160:23 161:6	153:11 157:22	17:15 26:23 29:15	<b>frankly</b> 71:8	32:19 33:1,6,7
<b>feel</b> 40:3 62:22 63:7	<b>five</b> 27:9 76:9 103:9	29:22 30:6 31:5	102:21 123:17	39:7,10 40:21
79:2 95:21 96:11	108:7	31:15,22 32:7	128:9 143:12	44:21,25 48:16
97:13 133:8 142:1	<b>fix</b> 145:20 146:1	33:20 37:24 38:5	150:18 151:11,15	58:20,23 62:9,13
172:24	<b>fixed</b> 104:20	40:22 43:2,20	154:24 160:3	85:9,18,24 87:8
<b>feels</b> 47:15 83:21	<b>flat</b> 163:4	44:4 46:2 47:23	166:5	94:24 95:2 99:1
<b>fell</b> 58:7 133:6	<b>flatten</b> 163:10	52:15,24 53:16	<b>free</b> 131:7	99:11 107:10
<b>fellow</b> 145:9	<b>flexibility</b> 118:23	54:3,21 57:12,14	<b>freedom</b> 68:8	110:21 114:5
<b>fellows</b> 34:25 35:5	<b>floor</b> 40:3 77:21	59:24 62:8 64:8	<b>french</b> 53:19,22	120:16 125:3,4
37:6,9 81:10	92:21 146:15	64:21 65:2 66:2	55:17	126:2 134:19
169:4	158:18	66:19 68:23 74:18	<b>frequently</b> 69:11	136:7,25 137:12
<b>fellowship</b> 34:22	<b>fly</b> 154:5	75:12 80:10 81:1	75:1 92:3 145:18	138:16 145:12
<b>felt</b> 133:2	<b>folder</b> 7:22 22:5,6,7	82:18 83:6,18,24	155:8 165:25	147:2 150:17
<b>female</b> 34:24	86:4	84:5,15 86:17	169:15 174:25	159:16 160:20
<b>fibers</b> 118:7	<b>folders</b> 17:18 20:5	87:18 88:16 89:9	177:2	169:11 174:1,23
<b>fibromyalgia</b> 141:3	<b>follow</b> 69:24 70:12	89:24 90:9,20	<b>front</b> 14:21 17:6	<b>generalization</b>
<b>fibrosis</b> 137:19	72:9 96:6 125:19	91:11 93:1 94:2	19:3,9 48:11 61:9	125:8
<b>field</b> 85:14,15,16	146:11,12 148:19	97:1 99:24 105:20	65:22 102:25	<b>generally</b> 16:19
86:2	153:10,16	111:7 115:22	103:8	26:20 27:14 68:17
<b>fields</b> 169:25	<b>followed</b> 54:9	116:10 117:18	<b>full</b> 4:22 18:2 19:3	85:6 94:3 102:17
<b>file</b> 1:3	55:13,24,25 56:7	120:6,25 134:24	20:22 55:1 75:6	115:10,10 126:8

130:2 138:15 169:9 170:15 <b>geometry</b> 167:10 <b>getting</b> 29:1 68:12 79:11 114:24 119:17,20 135:22 139:22 <b>giselle</b> 20:11 21:11 21:18 <b>give</b> 26:16,20 38:15 39:15 51:5 55:1 65:21 75:23 81:24 94:13 132:23 148:12 156:19,20 159:25 161:4 <b>given</b> 5:25 13:3 15:11,12,20 20:18 20:19 21:1 24:6 26:1 28:9 29:3 30:5 32:10,13 50:5 65:16 79:14 86:5 101:17 140:18 178:3 179:7 <b>giving</b> 25:21 101:4 <b>glad</b> 170:13 <b>glean</b> 45:1 53:17 <b>global</b> 127:22 <b>globally</b> 172:7 <b>glue</b> 105:1 <b>gmail</b> 2:8 <b>go</b> 7:10,15 9:12 16:23 19:20 20:1 28:10 29:6 30:2 31:1,10,11,19 32:2 38:25 41:1 42:2 44:10 46:22 61:13 62:1 74:2 74:25 94:15 113:13 131:18 134:8 135:13,19 136:6 138:17 139:12 143:17 149:7 157:17,23 163:2 174:22 <b>goal</b> 46:21 58:9	122:15 124:21 148:6 <b>goals</b> 145:25 <b>goes</b> 28:15 60:25 64:4 73:14 122:5 124:4 <b>going</b> 5:7 6:11 9:19 11:10 16:25 18:13 22:6 28:16 34:23 35:18 43:5 47:9 49:15 51:7,10,16 60:10 61:4,7 70:2 70:8,9 79:13 98:17 101:2 111:19 113:22 114:9 115:19,23 120:8,10 126:3 129:8 132:16 133:3 134:3,23 138:6 140:24 142:19 146:13 148:9,12 149:7,17 151:6 153:10 154:3,15 156:22 156:23 157:4,5,8 157:11,12,12,15 158:1 160:17 164:20 169:16 177:7 <b>golkow</b> 4:5 <b>good</b> 47:21 49:3,21 60:24 61:10 72:13 77:4 110:24 126:22 140:15 152:23 <b>goodwin</b> 1:5 <b>govern</b> 97:9 <b>governing</b> 97:19 <b>government</b> 64:2 65:10 <b>governmental</b> 64:16 <b>grade</b> 45:6 137:16 <b>graft</b> 72:5 100:2 119:21 <b>granulation</b> 137:3	<b>great</b> 122:4 <b>greater</b> 49:12 50:7 90:24 126:12 127:21,24 135:10 <b>gross</b> 41:25 42:12 <b>group</b> 40:23 43:13 47:14 53:19,23 54:23 55:6,12,13 55:17 65:11 76:7 78:9 81:11 86:19 86:19 93:7,11 106:17,20 109:1 110:8 113:19 123:1,2,10 124:7 124:11 128:10,12 131:16,22,24 132:25 133:11,16 138:13,14,15 140:22 141:10 142:16 143:7,7,8 147:19,20,21 148:16,23 149:25 150:23 155:15 176:21,23 <b>groups</b> 46:6,7 47:18 70:14 132:24,24 152:13 162:3 <b>guess</b> 42:23 <b>guidance</b> 28:21 <b>gyn</b> 176:13,14 <b>gynaecology</b> 15:24 <b>gynecare</b> 51:3 52:7 79:10 92:21 <b>gynecologic</b> 85:2 158:24 <b>gynecological</b> 36:11 45:22 117:21 <b>gynecologist</b> 16:15 <b>gynecologists</b> 61:19 175:17 <b>gynecology</b> 16:6 59:6 103:14,20 104:3,6 109:1 122:13	<b>gynemesh</b> 52:7 53:1 104:18 112:10,21 113:4 158:19 <hr/> <b>H</b> <hr/> <b>h</b> 3:9 <b>hadnt</b> 110:2 <b>hale</b> 2:5 <b>half</b> 18:3 82:13 <b>halina</b> 122:13 <b>hamilton</b> 23:21 <b>hand</b> 179:13 <b>handed</b> 6:11 46:4 107:18 <b>hands</b> 50:8 <b>handwritten</b> 6:16 6:22 15:25 16:7,9 19:25 20:2 21:5 <b>handy</b> 170:17 <b>happen</b> 72:4 88:8 115:2 116:8 134:20 138:2 142:20 <b>happened</b> 42:3 59:3 61:21 65:12 92:15 121:11 129:24 131:8 163:24 <b>happens</b> 60:2 61:3 116:6 121:3 124:3 129:21 132:3 149:6 162:21,24 <b>happy</b> 138:25 139:2 158:7 <b>hard</b> 74:11,23 123:3 <b>harm</b> 146:24 <b>harmed</b> 82:25 147:1,6 <b>hasnt</b> 84:6,23 149:11 152:21 <b>havent</b> 13:4 26:19 40:4,24 43:9 49:25 50:18 56:7 63:11 64:1 69:14	72:1 95:1 98:2 131:2 156:13 159:12 <b>head</b> 115:7 <b>heal</b> 116:15 138:1 <b>healing</b> 68:12 105:10 119:24 <b>heals</b> 135:21 <b>health</b> 110:14 131:25 <b>heard</b> 54:15 <b>hearing</b> 128:14 <b>heart</b> 116:2 <b>heed</b> 85:2 158:23 <b>held</b> 4:7 74:14 <b>help</b> 121:14 147:7 <b>helpful</b> 19:16 30:20 54:25 55:4 124:16 142:22 147:18 <b>hereinbefore</b> 179:6 <b>hereunto</b> 179:13 <b>hernia</b> 85:2,5,9,14 85:21 145:22 146:1,10 158:24 159:1 171:17 <b>hernias</b> 145:20 <b>hes</b> 8:10 78:10 157:4 <b>high</b> 27:3 70:7 125:1 141:11 166:11 <b>higher</b> 129:8 <b>highlighted</b> 22:9 86:6 163:23 164:3 <b>highlighting</b> 16:16 16:17 20:1,2 22:11 <b>highly</b> 86:19,20,20 <b>hinoul</b> 23:1,2 <b>historical</b> 173:2 <b>historically</b> 58:6 <b>history</b> 74:3 141:2 141:11 164:6 173:1 <b>hold</b> 17:8 59:6 105:1
--	--	---	---	--



<b>home</b> 9:7 163:25	141:19 172:8	132:9 133:3,13,16	<b>incision</b> 61:21	136:17 140:25
<b>honest</b> 27:4 47:24	<b>ideas</b> 46:22	136:17 138:8	154:4	159:3
<b>honestly</b> 12:12 27:1	<b>identical</b> 13:23	143:4 145:19	<b>incisions</b> 116:15,15	<b>infections</b> 80:4
<b>hoped</b> 104:16 106:5	14:2 99:16	148:3,11,12	<b>include</b> 27:24 94:11	164:8
<b>horizon</b> 45:17	<b>identification</b>	149:19 151:5	94:21 98:6,9	<b>inflamed</b> 137:6,7
<b>hospital</b> 89:15,22	141:22	152:2 153:9 155:1	136:11 165:3	137:10
144:3 160:12	<b>identified</b> 57:11	156:11,17,18	168:18	<b>inflammation</b>
<b>hospitalbased</b>	93:17 121:23	157:1,5,12 158:4	<b>included</b> 42:11	115:20 116:4,17
89:16	141:11 155:8	158:4,5,6,7 162:7	93:20 94:6,6	136:11,12,15,18
<b>hospitals</b> 89:13,22	159:11,14	162:12 164:7	123:8	137:7,10
160:8,16	<b>identify</b> 4:12 136:4	165:7 168:16	<b>including</b> 35:23	<b>inflammatory</b>
<b>host</b> 16:12 170:25	141:24 149:22	171:12 174:6,8	36:20 47:3 64:12	120:1,3 130:18
<b>hour</b> 6:24 11:20	151:4	<b>immediate</b> 26:2	84:19,22 114:10	171:7,7
102:14	<b>identifying</b> 68:3	152:18	116:16 134:8	<b>inform</b> 28:6 91:16
<b>hours</b> 6:23 9:11,18	<b>ifu</b> 79:19 97:16	<b>immediately</b>	158:19 170:18	<b>information</b> 7:22
11:19 102:13	98:3,6,8 140:21	142:11 155:8,10	171:6 172:5,11	8:1,5 10:4 39:2
157:17,18,19,21	140:23 141:1	<b>impact</b> 116:5	<b>inconsistent</b> 59:16	44:17 47:1 52:5
157:22	163:13,15 164:5	<b>implantation</b> 51:23	62:15,17 119:2,8	53:7 55:7,15,21
<b>houston</b> 2:14	172:4,10	111:24 137:20	<b>incontinence</b> 37:3	56:12 63:25 65:12
<b>human</b> 110:14	<b>ifus</b> 97:9,19,22,23	162:14,16 166:24	41:3 68:25 69:5	65:15 66:4,8,14
171:10	172:1	172:20 175:7	69:12,16	73:10,13 74:1,12
<b>humans</b> 85:20 97:7	<b>ignore</b> 5:9	<b>implanted</b> 28:5	<b>incorporate</b> 95:18	74:13,19,24 75:8
<b>hundred</b> 143:8,9	<b>ii</b> 110:17	35:22 43:15 113:5	<b>incorrect</b> 27:7	75:10,15,22 83:13
<b>hundreds</b> 61:20	<b>ill</b> 9:2 21:9 48:16	116:11 135:25	<b>incorrectly</b> 12:9	91:25 98:9 107:25
163:1	72:5,15 73:15	136:10 167:3	<b>indefinitely</b> 153:17	108:3 110:10
<b>hurt</b> 133:8 151:7,9	75:23 76:25 77:11	<b>implanting</b> 140:2	<b>independent</b> 31:1	111:10 113:9
<b>hydrodissection</b>	78:8 98:11,12	176:8	31:19 32:2 108:9	130:1 136:24
79:18,19	103:9 132:11	<b>implants</b> 43:1	<b>index</b> 138:19	139:15,25 140:18
<b>hymen</b> 49:6	167:23	<b>implemented</b> 53:14	<b>indicate</b> 113:9	140:18 147:11
<b>hypothetical</b> 88:2	<b>im</b> 4:4 5:3,7 6:11	<b>important</b> 118:20	160:25	158:20 164:3
151:22 152:3	8:15 10:14,15	144:14 148:25	<b>indicated</b> 42:5 53:2	168:24 170:10,11
<b>hysterectomy</b>	11:10 12:6,10	149:13 154:3	62:10 128:9	172:4,10 173:2
153:25,25 154:4	15:6,7 18:21	172:5,7,11	167:21	174:18
	25:17 28:16 30:8	<b>impossible</b> 143:2	<b>indication</b> 109:25	<b>informed</b> 55:18
<b>I</b>	35:17 37:7 42:23	<b>impression</b> 139:4	126:14	56:13 76:23 80:1
<b>id</b> 86:5 170:13	43:8 51:3,16 56:9	<b>improve</b> 46:18 77:6	<b>indications</b> 55:8	140:1 170:11
<b>idaho</b> 143:9	56:10 60:16,20,23	106:5 124:20	<b>individual</b> 26:4,20	172:12
<b>idea</b> 21:25 22:23	63:6,7 64:7,9,23	<b>improved</b> 128:17	50:2 52:9 60:8	<b>informing</b> 54:24
26:21 28:18 76:8	65:5,8 67:14,17	128:23	64:10 80:25 89:17	<b>ingrid</b> 131:5
93:11 114:6	72:10 78:9 80:21	<b>improvement</b> 46:9	<b>individuals</b> 40:9	<b>ingrowth</b> 167:7
126:22 143:12	87:19 90:15 94:13	59:11 161:23	89:12 102:4	<b>inguinal</b> 85:9
144:8	94:17,22 95:10,12	<b>inappropriately</b>	<b>industry</b> 97:18	145:20,22 159:2
<b>ideal</b> 46:24 48:23	97:10,11,13,13	86:9 87:24 88:12	175:1	<b>inhales</b> 166:13
55:11 78:21	101:2 107:3,4	159:22 160:6	<b>inert</b> 116:3,8,13	<b>inherent</b> 161:9
115:25 116:5	111:3,11,11,19	<b>incidences</b> 159:7	<b>infected</b> 85:7,11	<b>inhouse</b> 93:14
<b>ideally</b> 58:9 78:14	128:7,11 129:25	<b>incise</b> 135:24	<b>infection</b> 79:12	<b>initial</b> 54:1 55:17

109:10 <b>initially</b> 55:25 83:11 106:24 152:22 <b>injecting</b> 79:17 <b>injured</b> 146:17 <b>injuries</b> 47:3 56:3 <b>injury</b> 90:22 104:5 135:23 159:20 <b>innervated</b> 114:25 120:8 <b>innovation</b> 78:13 <b>input</b> 176:24 <b>insertion</b> 59:14 62:13 118:25 119:6,10 <b>institution</b> 50:18 <b>institutional</b> 79:25 80:5,17 <b>instruct</b> 28:16 <b>instructions</b> 167:17 172:1 <b>instrument</b> 60:23 61:6,22 <b>instruments</b> 21:15 60:9 61:3 162:15 <b>insufficient</b> 51:22 111:23 <b>intend</b> 163:2 <b>intended</b> 55:2 66:7 70:25 83:4,17 84:4 <b>intentional</b> 166:15 <b>intercourse</b> 129:18 <b>interested</b> 46:8 179:11 <b>internal</b> 14:6 104:4 108:12 <b>internally</b> 93:18 <b>international</b> 15:24 37:16 103:24 174:23 <b>interpret</b> 30:16 140:12 <b>interstate</b> 110:19 <b>interval</b> 166:4	<b>intervention</b> 49:16 131:24 133:18 134:11 138:4 <b>interventional</b> 103:13 <b>interventions</b> 133:23,23 <b>intrinsic</b> 68:13,13 <b>introduced</b> 115:19 130:16 <b>introduction</b> 51:22 58:4 91:19 111:23 128:2 147:15 152:5 <b>invasive</b> 104:6 <b>inventor</b> 92:20 <b>investigate</b> 140:13 <b>investigators</b> 171:4 <b>invoice</b> 6:5,16,22 7:1 10:11,18 11:11 27:25 101:25 102:2 <b>invoiced</b> 10:11 26:19,20 <b>invoices</b> 3:13,17 26:25 <b>invoicing</b> 10:8 <b>invoke</b> 120:1 <b>involve</b> 40:19 56:23 134:7 <b>involved</b> 29:1 40:19 87:11 97:10 106:8 153:9 <b>involving</b> 40:20 59:15 62:14 119:7 <b>irreversibly</b> 129:4 <b>isnt</b> 24:18,20 25:17 30:9 32:12 48:24 49:14 61:1 62:2 70:7,20 74:5 75:5 85:14 120:2 125:1 130:2 132:9 138:25 139:10 140:21 145:15 146:21 149:7 152:24 159:4,5	163:6 <b>isolated</b> 141:5 <b>issue</b> 38:7 48:15 59:12 61:11,12 63:25 70:8 86:6 88:7 92:15 111:12 130:10 139:10 143:2 149:1,14 152:12 <b>issues</b> 74:3 85:25 88:4 108:19 123:4 130:13 146:15 147:1 154:2,14 169:13 172:23 <b>italy</b> 93:4,6 <b>item</b> 128:1,15 <b>items</b> 168:25 <b>iteration</b> 122:2 <b>iv</b> 166:13 <b>ive</b> 5:25 12:10 14:25 28:22 35:20 37:12 39:12 67:11 70:23 71:5,6,10 71:15 72:2 77:22 86:21 96:6 98:2 101:8 120:14 144:17,17 145:12 155:19 157:19,20 163:1 173:14,15	<b>jones</b> 23:21 <b>joseph</b> 1:5 <b>josephine</b> 25:16 <b>journal</b> 15:1,24 16:15 32:3 33:18 34:4,16 37:17 81:8,8 103:14,19 103:24 104:3,6 108:25 122:12 <b>journals</b> 31:6 131:6 <b>judge</b> 1:6 <b>julian</b> 59:9 73:3 117:7,19 <b>june</b> 104:7 <b>justifiably</b> 141:13 <b>justification</b> 106:9	35:17,17 36:4,16 36:16,17,19 38:22 38:22 40:4 42:2 47:2,6,6 48:18 53:9,10,24 54:4 55:16,20,23 56:6 64:3,17,23 65:4,5 65:17,24 66:20 71:25 73:6,22 75:6 78:12 80:15 80:22,24 81:2,18 81:20 83:7,7,19 84:1,6 87:19 88:10,19 89:10,10 89:18,20,25 90:6 90:11,23 91:1 92:23 93:2,2,7 96:1,3 97:11,12 97:20,23 100:15 100:22 109:4 110:6 117:20,23 118:8 119:25 121:1,11,19,24 122:1 123:3 127:18,20,20 128:5,8,13 135:12 135:14 136:14,15 136:18 137:6,11 139:10 142:2,2,17 142:18,21 143:16 144:6,12,16,18 145:11 147:9,10 149:5,21,24 150:2 150:2,3,11,13 151:6,14 153:4,6 153:14 154:3 156:13 157:1,4 162:20,22,24,25 164:17 165:20,21 169:15 173:14 175:2 177:1 <b>knowing</b> 172:7 <b>knowledge</b> 28:20 30:1 32:21 33:2 40:11 41:21 52:17 74:21,21 81:23
--	--	---	--	---

Bobby Lewis Shull, M.D.

Page 194

87:3 88:23 92:17 93:9 95:6,14 100:4 110:7 111:8 119:19 142:7 147:3 150:13 159:17 173:7,23 174:13 176:18 <b>knowledgeable</b> 9:14 63:21,23 65:5 76:4,6 78:10 96:12,12,15 <b>known</b> 153:3	<b>learn</b> 42:3 55:2,8,9 73:13 80:2 148:8 <b>learned</b> 149:16 154:5 169:1 <b>learning</b> 46:23 53:12 124:2,4 125:17 135:2,3 149:23 <b>leave</b> 170:20 <b>leaving</b> 158:14 <b>lecturing</b> 145:19 <b>left</b> 7:25 17:17 100:19 113:4 114:10 <b>legal</b> 28:19,25 72:6 88:3,7,10 143:13 <b>legally</b> 89:11 <b>lend</b> 45:2 <b>length</b> 42:11 140:8 151:21 152:3 <b>lesser</b> 83:9 <b>letter</b> 63:22 110:15 121:7,9 <b>level</b> 58:19 83:12 84:18 86:21 89:20 90:21,23 119:19 132:20 134:5,6,11 137:16,18 172:25 <b>levels</b> 83:8 160:1,3 <b>lewis</b> 1:10 3:3,12 4:18,24 178:8 179:5 <b>liability</b> 1:4 <b>licensed</b> 88:15 <b>lie</b> 163:6 <b>life</b> 74:7 126:7 131:20 132:1,21 133:22,25 134:16 134:21 143:1 151:19 <b>lifealtering</b> 131:10 <b>lifechanging</b> 130:23 133:19 <b>lifelong</b> 142:25 <b>ligament</b> 135:20 <b>ligaments</b> 165:18	165:18 <b>lightweight</b> 171:15 <b>likelihood</b> 79:11 105:7 114:23 124:17 126:17 127:3,6 129:5 147:5,7 <b>limit</b> 153:7 <b>limited</b> 45:16 58:22 140:19 175:15 <b>limiting</b> 55:5 <b>linda</b> 41:10 <b>line</b> 169:25 180:3 181:2 <b>list</b> 5:21 24:15,16 25:4,6,10 102:8 130:23 <b>listed</b> 29:11 102:2 <b>listen</b> 32:1 <b>listening</b> 173:16 175:18 <b>listing</b> 110:24 <b>literature</b> 7:16 8:14 8:17 13:15 14:5 14:20 19:3 29:7 30:3,8 39:4,4,17 41:14 44:2,7,13 44:16,22 45:7 48:12 53:1,18 72:13 81:8,17 85:3,17,18,19 92:1 97:21 100:24 102:9 105:21 108:15 122:7 127:11 128:16 139:11 143:6 158:24 167:13 168:4,6,11,17,18 170:4 171:20 173:8,21,24 <b>litigation</b> 1:5 12:3 14:13 24:8 26:17 28:7 29:2,4 35:9 43:18 <b>little</b> 6:23 51:4 66:16 107:5 120:9	149:25 <b>live</b> 93:5 <b>livenote</b> 1:21 <b>lives</b> 131:8,19 135:5 <b>living</b> 53:6 <b>llc</b> 2:3 110:16 <b>llp</b> 1:16 2:11 <b>local</b> 79:20 81:13 120:3 130:18 166:12 <b>locate</b> 15:10 <b>location</b> 1:16 105:11 <b>long</b> 9:9 22:23 55:14,24 56:11 58:17 70:13 75:2 139:22 146:11 148:19 149:3,4 153:5 <b>longer</b> 56:7 69:24 84:8 93:24 105:16 113:1 125:19 149:7 153:14 154:13 168:25 177:3 <b>longitudinal</b> 78:19 <b>longterm</b> 73:14 86:12 123:22 <b>look</b> 9:2 18:7 19:5 19:11 22:6,10 30:13,18 32:15 39:1,14 49:17 54:10 72:15,21,22 72:25 74:7 76:19 78:15 79:24 86:5 95:19 106:25 107:2 122:15,18 122:22 126:9,19 127:11 128:12,25 129:1 130:5 154:6 162:1 164:2 166:23,25 167:3,8 169:14 170:12,14 170:16,16 <b>looked</b> 9:16 20:2	39:12 54:7 63:9 66:25 97:25 98:1 122:14 123:10,18 149:15 171:4,5,8 <b>looking</b> 18:23 46:9 49:12 67:15 79:17 97:4,5 107:15 109:12 123:15 124:10,13 125:24 129:15 137:1 152:14 171:11,12 <b>looks</b> 6:15 10:9 66:18 101:24 103:23 174:19 <b>loop</b> 72:10 <b>losing</b> 18:21 63:6 <b>lost</b> 134:9 <b>lot</b> 53:21 96:1,3 99:10 121:19 127:6 129:15 143:10 144:14 146:19 151:14 <b>low</b> 129:4 <b>lower</b> 83:12 132:8 132:20 <b>lunch</b> 170:21 <b>lying</b> 136:3
<b>L</b>				<b>M</b>
<b>lab</b> 155:15,20 <b>labeled</b> 15:21 22:21 23:14 <b>labeling</b> 110:25 <b>laboratory</b> 63:9,10 66:9,23 67:22 <b>labs</b> 155:19 <b>lack</b> 57:6 68:8 75:17 78:24 135:23 140:8 144:25 <b>lacked</b> 158:17 <b>lacks</b> 77:20 <b>language</b> 164:17 <b>large</b> 115:23 117:6 138:12 171:15 <b>lasted</b> 139:22 <b>late</b> 58:21,24 <b>laudable</b> 46:21 <b>laughing</b> 70:3 <b>launched</b> 21:12 <b>law</b> 14:11,11 63:22 <b>lawyer</b> 26:7 144:2 144:15,21 161:3 <b>lawyers</b> 143:17,18 143:23 144:10 181:1 <b>lay</b> 28:10 114:16 163:3 <b>lead</b> 162:18 175:11 <b>leading</b> 172:22 <b>leak</b> 80:4				<b>m</b> 1:10,14 3:3,12,16 4:7 5:5 6:5,6,8,18 10:19 11:24 12:14 13:1,4,17,24 17:2 17:2,14 18:9 24:9 25:22 29:12 30:22 31:11 32:20 33:11 36:15 37:23 38:14 38:16 39:6,20,24 40:10,14 44:3,24 51:12,12,18,23 56:14 58:5 59:21 62:6 67:1 73:11 75:18 80:17 82:4 82:10,17,22 84:2 84:12 86:10 88:13 98:19,19,25 99:9

Bobby Lewis Shull, M.D.

Page 195

99:17,23 100:1,8 100:14,22 108:22 111:21 112:2,7,13 112:15,20,23 113:2,8,11,13 114:1,9,18 115:12 116:20 118:15 119:5,9 121:25 128:20 135:18 139:19 140:5 159:25 161:12,17 164:22,22 165:11 166:17,21 168:5 169:12,12 172:16 173:4,18 177:10 178:8 179:5 <b>maam</b> 172:3 <b>mac</b> 166:12 <b>magic</b> 145:16 <b>magnified</b> 61:6 <b>main</b> 113:15 <b>maintain</b> 109:22 <b>maintained</b> 90:18 <b>maintenance</b> 58:1 118:11 <b>major</b> 124:6 159:6 <b>majority</b> 15:14 140:20 <b>making</b> 17:13 67:9 88:23 100:16 148:11 172:6 <b>man</b> 146:2 <b>manage</b> 55:9 61:8 130:11 141:18,19 143:2 150:8,14,19 151:4,13 <b>managed</b> 131:13 <b>management</b> 73:12 130:21 139:17 <b>managing</b> 142:6 154:8 173:16 <b>manipulate</b> 163:5 <b>manufacturer</b> 12:11 64:4 95:7 95:15 <b>manufacturing</b>	63:13 110:24 <b>manuscript</b> 122:20 122:23 <b>march</b> 1:13 4:6 20:15 179:14 <b>marcus</b> 105:23 <b>margaret</b> 2:4 4:13 10:11,12 11:16 26:9 102:2,6,10 103:2 <b>mark</b> 6:11 105:24 <b>marked</b> 4:2 5:8,23 5:25 6:13 15:25 21:4 22:7 23:12 37:11,12 100:11 101:2,8,22 <b>market</b> 52:9 53:2 83:16,23 84:3,14 84:24 95:8,16 105:12,15 112:7 117:17,20 147:16 152:6 174:10,11 <b>marketed</b> 21:21 52:8 56:10 86:1,9 88:12 110:18 159:22 160:6 <b>marketing</b> 17:23 92:21 174:10 <b>marks</b> 51:14 98:21 164:24 <b>markups</b> 16:8,10 16:16,17 <b>marlex</b> 117:8,19 118:1,7 <b>master</b> 1:3 <b>matches</b> 101:25 <b>material</b> 15:9,10 69:18 72:6 100:2 100:7 116:8 117:24 119:23 144:2 170:4 171:5 171:21 <b>materials</b> 17:24,24 58:16 171:16 <b>matter</b> 4:8 9:15 10:2 56:2 71:9	107:9 134:8 <b>matters</b> 25:4 <b>maude</b> 90:10 <b>maximum</b> 157:13 <b>mckinney</b> 2:13 <b>mdl</b> 1:4 4:14 <b>mean</b> 21:6 32:16 40:15 41:22 44:8 44:17 60:15 76:22 88:4 114:1 132:22 134:14 139:9 161:25 <b>meaning</b> 21:14 <b>means</b> 44:14,16 123:1 134:1 152:16 <b>meant</b> 35:21,21,22 <b>measure</b> 41:24 123:16 <b>measures</b> 67:16 <b>mechanism</b> 64:18 105:3 <b>medical</b> 7:15 8:17 14:20 15:10 17:11 17:23 19:3,8 29:7 30:2 31:2 32:3 33:18 34:4,16 39:4 41:13 62:25 63:13,20 64:3 65:25 72:12 79:8 81:8 82:6 83:2,15 83:21 85:13 86:15 87:23 90:8,19 91:9,12 93:24,25 95:7,15 96:5,21 96:22,23 110:20 119:10 122:7 128:16 129:6 137:20 145:2 167:13 170:4 173:8,21 <b>medication</b> 79:21 <b>medicine</b> 34:24 88:7 118:9 142:16 <b>medium</b> 123:21,24 <b>mediumterm</b>	103:21 <b>meet</b> 9:4,19,24 <b>meeting</b> 81:10 174:24,24 175:16 <b>meetings</b> 91:6,9,13 91:21 174:14,22 <b>meets</b> 63:22 <b>meghan</b> 11:16 <b>mellitus</b> 141:4 <b>member</b> 176:25 <b>memory</b> 19:7 121:22 <b>mentioned</b> 19:6 129:2 158:12 <b>mesh</b> 12:3 14:13 15:23 21:15 24:7 28:5,7 29:2 33:13 33:13 35:9,13,21 35:24 36:2,11 40:20 41:7,9,14 41:17,18 42:7 43:1,6 46:1 47:16 47:16 48:5 49:10 49:10,24 50:7,12 50:18 52:3,7,9,19 52:22 53:4,23 54:9 56:21,22,24 57:20 59:5,8,13 59:14 60:1 61:23 62:13 66:23,25 67:4,21 68:11,20 68:22 70:20,21 72:14,17,18,19,20 72:24 73:1,5,6,19 75:25 76:10,21 77:7 85:3,19 86:2 86:13,19,23 87:9 93:3 95:24 100:19 103:12,18,23 104:2,5,22 105:4 105:7,7,23 106:2 106:14 109:3,5,6 109:11,15 111:11 111:13,16 112:23 113:20,22 114:8 114:21,23,23	115:12,14 117:15 119:1,6,14 120:5 120:7,7 123:5,18 124:8,12 125:9,18 126:1,4,8,12,16 126:17,22,23,25 127:6,13,20,22 128:18 129:3,5,6 129:10,16 130:8 130:12,16,16,20 130:25 132:11,19 135:16,19,22,25 136:9,16 144:9 145:13 150:21,22 153:5 154:21 156:5,5,14 158:11 158:25 159:2,4,7 159:23 160:6 161:13,15 162:15 162:18 163:3 165:15 167:6,7 169:3,4,9,13,16 169:18 170:5 172:20 173:20,25 176:5,8,12,15,19 176:20 177:1 <b>meshes</b> 57:1,2,3 171:17 <b>message</b> 30:19 <b>met</b> 4:25 9:6,7 <b>method</b> 47:7 64:6 <b>michigan</b> 138:14 143:8 <b>microscope</b> 67:1 <b>microscopic</b> 42:16 42:17 71:20 171:5 <b>mid</b> 58:21 <b>midurethral</b> 41:23 50:15 61:16,18 67:25 69:9,17 163:1 176:15 <b>milan</b> 93:6 <b>mind</b> 27:21 78:1,6 99:22 100:12 148:24 170:13 <b>mine</b> 89:1
---	---	--	---	---

<b>minimally</b> 104:6 <b>minimize</b> 79:11 80:3,3 105:6 109:9 127:6 <b>minimized</b> 100:20 <b>minimum</b> 88:20 123:20 <b>minute</b> 16:24 33:22 157:24 <b>minutes</b> 9:25 11:12 11:13,14,15,16,18 11:19,20 18:18 19:2 102:9,10,13 102:14 <b>misbranding</b> 110:25 <b>missouri</b> 81:12,20 <b>mistaken</b> 12:6 65:8 <b>model</b> 16:14 40:24 97:4 171:2,9 175:6,19 <b>models</b> 85:20 175:8 <b>modification</b> 112:15,16 <b>modifications</b> 55:7 <b>modified</b> 98:9 <b>moment</b> 72:16 107:10 170:21 <b>monitor</b> 78:7 90:2 160:21 <b>monitoring</b> 86:24 90:7 161:5 <b>monocryl</b> 100:18 112:25,25 113:2 <b>month</b> 152:20 169:12 <b>months</b> 56:2 113:3 123:23,23 129:24 153:12,12,14,18 166:5 <b>morbidity</b> 52:5 74:10 139:24 <b>morning</b> 5:4 9:8,20 9:24 10:2 98:24 100:7 108:20 124:15 170:19,20	<b>morphed</b> 118:4 <b>mother</b> 149:19 <b>motley</b> 2:3 <b>mount</b> 154:1,1 <b>move</b> 105:8 <b>movement</b> 61:5,5 <b>mthompsonmd</b> 2:8 <b>multicenter</b> 80:21 81:11 154:18 <b>multiple</b> 31:6 133:23 134:6,7,13 134:14,15 <b>muscle</b> 53:4 57:17 60:5 113:14,19,22 114:10,13 120:10 <b>muscles</b> 62:1 114:19 135:21 146:17 <hr/> <b>N</b> <hr/> <b>n</b> 2:1 3:1 4:1 <b>name</b> 4:4,22,25 11:7,9 23:1 25:9 43:14 97:3 112:24 113:1 122:5 144:21,22 <b>names</b> 108:7 144:22 <b>narrow</b> 139:23 <b>native</b> 45:9 56:19 69:6,8 76:15,17 165:14 <b>natural</b> 74:3 <b>near</b> 165:18 <b>necessarily</b> 74:25 125:22 130:18 <b>necessary</b> 55:7 57:22 65:16 136:20 <b>need</b> 26:2 53:13 61:20 77:5 78:7 79:22 104:21 123:19 126:11 141:13 143:14 152:10 <b>needed</b> 91:24	168:24 <b>needle</b> 60:24,25,25 <b>needs</b> 83:3 125:15 130:1 <b>neighborhood</b> 35:18 133:7 <b>neither</b> 83:21 84:13 179:9 <b>nerve</b> 60:6 165:18 <b>nerves</b> 114:11,19 120:5 146:17 <b>never</b> 48:21,21 60:3 85:12 116:6 145:25 151:16 <b>new</b> 52:14,19 53:3 53:6 54:19 66:3 109:21 131:18 159:20 <b>newer</b> 66:12 <b>nine</b> 6:23 <b>nonabsorbable</b> 100:1,18 <b>nonanchored</b> 103:18 104:2,5 105:23 106:2 <b>nonbenefit</b> 158:15 <b>nonmesh</b> 126:6,8 <b>nonphysician</b> 91:6 <b>nonresponsive</b> 62:3 87:13 90:13,14 151:20 156:2 <b>nonsurgical</b> 96:5 <b>nontrocar</b> 113:20 174:6 <b>normal</b> 28:20 58:10 58:11,19 132:3 <b>normally</b> 42:9 58:15 60:3 95:25 123:5 132:14 144:15 166:3 <b>norms</b> 54:19 <b>notary</b> 178:18 <b>note</b> 21:5,20 36:18 121:4,18 122:3 <b>noted</b> 178:5 <b>notes</b> 6:17,22 16:1	16:2,7,9 18:25 19:25 20:2 181:1 <b>notice</b> 3:11 5:8,11 5:15 <b>noticed</b> 19:24 59:10 59:12 <b>number</b> 17:18 22:3 42:11 45:12 52:10 78:18 148:18 156:18,19,20 <b>nygaard</b> 131:5 <hr/> <b>O</b> <hr/> <b>o</b> 4:1 <b>object</b> 13:5 14:23 17:15 26:23 29:15 29:22 30:6,23 31:5,15,22 32:7 33:20 37:24 38:5 40:22 43:2,20 44:4 46:2 47:23 52:15,24 53:16 54:3,21 57:12,14 59:24 62:8 64:8 64:21 65:2 66:2 66:19 68:23 74:18 75:12 80:10 81:1 82:18 83:6,18,24 84:5,15 86:17 87:18 88:16 89:9 89:24 90:9,20 91:11 93:1 94:2 97:1 99:24 105:5 105:20 111:7 115:22 116:10 117:18 120:25 134:24 136:22 137:21 140:11 143:20 144:11 147:17 162:23 166:18 176:9 <b>objection</b> 13:10 28:12 38:18 62:3 87:13 90:13 151:20 156:2,21 156:25 169:6,21	171:23 172:18 173:22 174:2,16 <b>objections</b> 5:18 <b>objective</b> 53:7,10 67:16 70:6 74:6 <b>obligation</b> 141:24 <b>obliged</b> 84:10 <b>obliterate</b> 58:8 <b>obliteration</b> 58:13 <b>observation</b> 68:4 69:2 132:10 <b>observations</b> 28:24 53:22 54:13 67:23 78:20 <b>observe</b> 72:11 <b>observed</b> 67:24 71:18 <b>obstetricians</b> 175:17 <b>obstetrics</b> 15:24 16:6,15 103:14,19 104:3 109:1 122:13 <b>obtain</b> 172:25 <b>obtained</b> 87:4 106:4 174:18 <b>obtaining</b> 172:12 <b>obvious</b> 90:4 140:20 <b>obviously</b> 117:9 <b>occasionally</b> 166:14 <b>occur</b> 55:10 78:7 116:16 138:11 142:12 151:12,13 161:9 <b>occurs</b> 75:2,2 120:3 127:18 142:5 165:19,21 166:14 <b>october</b> 103:15 <b>offer</b> 96:4 116:24 127:13 <b>office</b> 166:9 <b>oh</b> 10:23 39:15 <b>okay</b> 5:7,13 6:11 7:1 8:12 9:3
---	--	---	---	--



Bobby Lewis Shull, M.D.

Page 197

12:19 13:13 14:9 15:17 16:4 18:18 22:14 25:2 26:16 27:17,20 29:19 34:15 35:7,19 36:14 47:20 63:4 71:11 89:2 92:11 94:19 99:4 101:13 101:17 102:8,17 107:11 108:12 120:22 133:10 136:9 146:19 157:14,23,25 <b>old</b> 155:23,24 <b>older</b> 140:23 <b>omission</b> 5:22 <b>once</b> 5:9 16:7,15 22:14 23:3 46:24 47:18 65:9 102:1 116:11 119:22 130:16 132:3 138:20 142:11 <b>onepage</b> 23:13 <b>ones</b> 7:19 25:6 31:2 31:13,20 32:23 119:15 131:10 133:1,2 139:3 156:12 160:9 172:3 <b>oneyear</b> 56:3 107:12 122:10 <b>online</b> 103:25 <b>onset</b> 152:15 159:21 <b>opening</b> 49:6 <b>operate</b> 68:1 72:5 154:25 155:17 <b>operated</b> 61:20 72:2 109:2 123:14 124:7 149:3 155:20 173:14,15 <b>operating</b> 61:18 155:21 <b>operation</b> 47:12,13 60:18 69:10 71:5 73:16 129:21	147:25 149:2,19 152:17 160:2 <b>operations</b> 69:18 145:23 148:17 <b>operative</b> 36:18 121:18 122:3 169:14 <b>operator</b> 60:14,15 <b>opined</b> 108:20 <b>opining</b> 111:11 <b>opinion</b> 33:2 51:21 54:18 56:14 62:21 75:5,20 77:7 82:2 82:21 85:25 87:6 88:11,25 89:1,3 90:1 111:22 116:18,19 118:14 119:4 128:15,19 172:15 <b>opinions</b> 12:25 13:3,23 45:8 51:17 54:12 78:23 92:5 94:24 111:19 111:20 168:20 170:9 <b>opportunity</b> 65:14 121:4 124:19 <b>opposed</b> 78:20 <b>option</b> 43:9,9 58:14 <b>options</b> 96:5 <b>oral</b> 14:14 81:18,21 <b>order</b> 18:15 20:23 23:17 28:10 57:21 64:4 70:11 78:8 83:15 88:22 94:20 126:21 132:13 163:10 <b>organ</b> 16:5 41:5 44:2 45:4 46:8 51:20,24 58:4,12 75:17 76:1 103:12 104:14 106:14 111:25 116:23 136:10 144:25 164:13 <b>organization</b> 42:8	81:13,22 <b>organizational</b> 50:24 <b>organizations</b> 50:25 <b>organized</b> 15:16 18:22 <b>organizing</b> 18:24 <b>original</b> 53:21 73:20 99:25 138:19 <b>originally</b> 68:9 <b>ought</b> 63:25 77:24 98:8 <b>outcome</b> 15:21 30:17 32:23 48:13 48:15,18 49:1,4 75:7 77:4 123:6 123:16 125:2,10 126:5 128:24 135:11 138:17,25 139:4 146:6,9 148:9 150:12 152:7 154:9 179:11 <b>outcomes</b> 32:25 46:5,10,14,19 49:7,11,19,20 52:6 54:11,16 56:3,4 60:17 69:7 69:16 73:14 74:9 76:20 78:11 82:24 103:17,21 106:6 107:12 109:5 122:11 123:3,10 123:16,22 124:14 124:20 125:1,8 126:2 127:17 128:17,24 139:12 139:24 147:24 <b>outside</b> 49:5 93:6 93:19 140:22 146:7 <b>outweigh</b> 45:24,25 <b>outweighed</b> 145:7	<b>P</b> <b>p</b> 2:1,1 4:1 98:19,19 164:22,22 177:10 <b>packaged</b> 21:14 <b>page</b> 3:10 20:16,17 20:17 21:1,1,10 22:2,21,21,22 23:10,11,12,12,14 23:22,24 94:15 101:23 103:1 171:13 180:3 181:2 <b>pages</b> 21:2 22:3,8 23:10,13,23,25 178:3 <b>paid</b> 10:10 <b>pain</b> 70:19,19 74:8 74:22,23 75:1,4,5 79:21 80:3 85:21 114:8,12,25 115:16 122:16,17 123:4 126:15 129:17,17,18,18 130:10,11,17,19 130:21 131:13,17 131:23 132:1 133:14,18 136:16 137:5 141:4 142:23,24,25 149:25 150:21 153:4 159:8,17,21 164:6,11 172:23 <b>painful</b> 137:6 <b>palpating</b> 67:8 <b>palpation</b> 172:22 <b>panel</b> 65:19,22 <b>paragraphs</b> 14:1 94:19 <b>parameters</b> 47:3 49:16,18 65:9 78:25 146:6 171:6 <b>pardon</b> 101:6 107:12 117:7 160:12 171:2 <b>parse</b> 111:3 <b>part</b> 18:21,22 30:12	31:24 32:11 39:16 40:7 61:8 64:18 79:18 91:15 98:5 98:6 112:25 114:7 123:9 134:25 151:6 170:24 171:25 <b>participant</b> 15:15 <b>participate</b> 54:23 175:18 <b>participated</b> 37:9 98:3 <b>particular</b> 18:25 22:5 42:8,14 45:6 54:22 61:4,8 87:9 109:24 135:4 144:3 170:13 175:11 177:2 <b>particularly</b> 77:14 145:18 168:23 172:3 175:6 176:25 <b>parties</b> 179:10 <b>partly</b> 32:9,10 130:10 <b>partner</b> 134:20 159:20 <b>partners</b> 132:5 <b>pass</b> 60:8 167:23 <b>passage</b> 59:15,21 60:1 62:14 110:4 119:7 <b>passed</b> 60:2 <b>patch</b> 57:6 <b>pathologic</b> 85:19 <b>pathological</b> 171:18 <b>pathologist</b> 42:13 71:23 <b>pathologists</b> 41:19 72:1 <b>pathology</b> 42:2,5 171:17 <b>patient</b> 28:4,5 37:6 37:7 45:1 48:1 50:3 69:22 70:8
---	--	--	---	---

Bobby Lewis Shull, M.D.

Page 198

70:10 71:2 72:6 75:4 76:6 79:22 86:12,12 89:4,6,6 100:19 120:13,17 120:23 121:19 122:3 126:7 134:23 138:6 139:8,8 140:2 145:12,15 146:11 150:15 151:1 152:12 155:5,6,6 166:5 172:8 <b>patient</b> 145:4 <b>patient</b> 145:4 <b>patients</b> 33:13 34:12,17,21 35:4 35:12 36:17 38:16 38:23 49:14 54:2 54:4,10,15,20,23 55:13,17,24 56:6 56:12 59:1 68:16 68:20 69:7 70:1 70:14,15,17 71:25 72:2 73:9 75:19 76:18,21,23 79:24 80:1 82:24,25 96:9 106:1,2,2,17 106:20,23 109:2 117:10 121:5,10 121:24 132:2 136:25 138:8,21 139:2,6,14 140:9 142:15 143:7,21 144:4,9 145:1,7 148:20,21 150:11 153:10,19 154:20 156:5,7 162:3 165:6 169:4 172:13 173:13 <b>paul</b> 40:5 <b>peer</b> 33:18 34:4 41:13 81:17 173:8 <b>pelvic</b> 1:4 16:5 34:24 40:2,20 41:5,14 44:2 45:4	46:8 49:24 51:20 51:24 58:4 59:17 62:15,17 73:22 75:17,25 77:21 92:20 95:23 96:1 96:13 97:5 103:12 104:14 106:14 109:21 111:25 114:8 116:23 119:2 130:24 136:10 144:25 146:15 158:18 164:6,11,13 <b>pelvic</b> 40:24 43:15,16 97:4 118:3,3 171:3 <b>pelvis</b> 52:18 53:21 54:5,8 62:1 66:5 109:20 113:19 114:17,19 116:3 119:18 125:14 135:21 165:19 <b>pen</b> 19:25 60:20 <b>penetrate</b> 52:18 113:18 114:18 <b>penetrated</b> 114:13 114:19 <b>penetrating</b> 104:20 <b>people</b> 34:23 39:16 39:22 43:7,13 45:17 46:13,20,25 47:5,10,12,14,24 48:25 53:6 55:6 60:13 62:22 63:8 69:15 71:5,6,14 73:25 76:13 85:21 86:23 87:8 90:10 91:16 96:4,4,6 117:12 121:15,19 123:2,14 126:1,19 127:1,6 132:7,12 133:11,16 134:13 134:18 135:1,2,10 137:6,12 139:5 140:22,23 141:12 141:21,23,25	142:16,18,21 143:3,10 144:7 146:19 147:8,19 148:9,10 150:23 151:7,9,10,15,15 152:10,25 154:17 155:15,20,21 158:22 160:1,3 164:16 175:9,16 176:17 <b>percent</b> 48:5 70:2,9 76:13,13 86:22 127:4,5 133:6,7 133:13,15,15 139:11 147:25 148:2,3,4,4,5,8 162:2 <b>percentage</b> 69:20 133:5 143:12 <b>percentages</b> 133:4 <b>perception</b> 49:15 <b>perforated</b> 38:9 <b>perforation</b> 3:15 37:14 38:3,7 73:22 <b>perform</b> 50:11 <b>performed</b> 26:2 57:5 97:21 116:23 117:4 128:6 138:19 <b>period</b> 36:2,6,8 54:10 55:14 70:13 73:2,24 78:14 79:14,22 105:5 113:3 134:5 <b>periodically</b> 71:13 72:4 <b>perioperative</b> 56:3 74:10 139:24 152:8,11 <b>permanent</b> 57:2 <b>permanently</b> 113:5 <b>persistent</b> 162:2 <b>person</b> 21:17 66:11 96:12,13 127:3 141:22 146:22	177:2 <b>personal</b> 50:4 77:8 132:10 173:15 <b>personally</b> 33:11 35:1,4 39:19 43:6 49:23 67:20 71:18 79:6 96:8 151:10 156:3 166:19,20 168:10 <b>personnel</b> 91:4 <b>persons</b> 25:9 <b>peter</b> 2:19 4:4 <b>phone</b> 11:16 102:12 <b>physical</b> 48:22 133:24 <b>physician</b> 25:11,19 38:4 62:19 86:15 87:15,22,25 88:5 88:15 89:5 90:3 90:11 91:17,18,21 91:21 120:16,18 123:8 156:8,12,13 160:13,23 161:6 <b>physicians</b> 39:23 53:14 54:15 55:12 55:23 75:19 86:10 86:11 87:1 88:6 88:13 89:17,21,23 90:5 91:10 105:22 145:1 159:23 160:7 172:6,12 174:10,11,12 175:10 <b>pick</b> 143:6 154:7 <b>picking</b> 135:13 152:12 <b>piece</b> 41:23 <b>piet</b> 23:2 <b>place</b> 52:22 54:1 56:25 60:11,11 61:13 65:6 90:2 104:21 105:1,4,9 113:17,18 119:18 119:21 140:13 151:23 155:9 <b>placed</b> 38:11 56:24	57:7 67:8,25 68:9 92:6 104:23 105:12 113:21 119:23 128:18 129:3 161:10 162:14,15 173:25 <b>placement</b> 38:8 104:17 161:14,16 161:19 <b>places</b> 57:22 125:14 <b>placing</b> 54:8 155:4 <b>plaintiff</b> 1:7 2:9 28:6 <b>plaintiffs</b> 4:14 15:17 17:12 18:15 19:16 20:8,9 22:16,17 23:4,20 24:8 28:7 29:14 29:21 30:5 31:3 32:5 35:8 82:15 92:8 108:4,8 161:3 165:2 <b>plan</b> 140:13 <b>plane</b> 60:22 61:4 <b>planes</b> 60:3,4 <b>planned</b> 138:3 <b>play</b> 157:15 158:1 <b>please</b> 4:12,23 107:15 162:12 <b>pliable</b> 164:9 <b>plus</b> 75:15 118:19 <b>pockets</b> 120:6 162:15 <b>point</b> 27:18 94:20 130:14 134:25 137:23 145:16 157:3 164:15 <b>pointed</b> 87:10 109:8 124:1 <b>pointing</b> 155:1 <b>points</b> 49:13 <b>polypropylene</b> 49:24 50:7,11,16 66:23 67:4,21 68:20 85:3 86:2 119:1,14 136:9
--	--	---	--	---

Bobby Lewis Shull, M.D.

Page 199

158:25 170:5 171:17,18,21 173:20 <b>poor</b> 46:10 54:6,6 124:18,19 <b>pop</b> 44:23 <b>popq</b> 164:15 <b>porcine</b> 16:14 171:1 <b>porous</b> 171:16 <b>portion</b> 23:3 100:2 100:17,18 105:8 111:5 112:23 114:16 <b>portions</b> 20:6,18,19 22:11,15 94:11 <b>position</b> 97:10,11 163:5,7 <b>positive</b> 15:7 168:22 <b>possession</b> 14:25 16:20 <b>possibilities</b> 119:16 <b>possible</b> 9:20 41:22 47:3 55:1,9 62:2 72:1 78:4,6 89:17 94:22 105:2 117:23 120:5 128:11 150:9 151:12 152:8 159:18,20 164:1 <b>poster</b> 81:15 <b>posterior</b> 15:22 49:5 70:18 127:14 127:19 161:21 <b>postoperative</b> 152:19 <b>potential</b> 26:1 52:6 55:2 60:12 90:22 90:24 110:6 141:6 158:14 174:20 <b>potentially</b> 104:12 130:22 <b>power</b> 147:22,23 148:7,16 154:13 154:16	<b>practical</b> 58:25 71:15 77:25 121:3 131:14 139:25 153:16 <b>practically</b> 43:4 70:7 122:3 143:1 <b>practice</b> 39:23,24 50:10 68:18 88:6 91:3 110:25 120:12 138:24 142:15 144:13,13 145:10 167:14 172:1 <b>practiced</b> 40:7 <b>practicing</b> 68:21 <b>practitioners</b> 145:9 <b>precursor</b> 161:22 <b>predicate</b> 64:13,13 64:15 66:11,13 109:19 110:12 <b>predict</b> 141:6 <b>predictable</b> 61:1 <b>prefer</b> 45:9 <b>preformed</b> 21:15 <b>pregnant</b> 140:24,24 <b>preoperative</b> 141:20 <b>preparation</b> 6:6 7:6 7:9,11 9:4 15:2 17:13,16 18:9 24:8 28:1 39:1,7 39:11 <b>prepare</b> 28:11 <b>prepared</b> 9:14 11:4 11:5 12:2,14,22 13:19 29:2 32:5 33:16 34:1,10,15 77:16 99:5,21 174:19 <b>preparing</b> 11:23 12:13,20 18:14 19:17 26:12 31:10 31:21 95:8,16 101:19 104:10 164:4 <b>preponderance</b>	51:2 <b>present</b> 2:19 28:23 62:14 91:15,22 93:3 <b>presentation</b> 7:9 81:15,19 <b>presentations</b> 93:13 174:19 <b>presented</b> 63:1 81:9,23 <b>presenting</b> 26:7 150:3 <b>presently</b> 11:9 71:11 <b>presents</b> 59:16 119:1,7 <b>presume</b> 60:10 76:5 83:25 114:7 141:23 146:8 <b>presuming</b> 141:8 148:8 <b>presumption</b> 68:10 100:16 <b>previous</b> 12:5,15 12:21 69:17 130:4 <b>previously</b> 14:25 18:24 39:12 53:2 57:16 66:14 68:6 76:17 78:13 110:3 176:25 <b>primarily</b> 12:23 46:9 56:19 60:5 74:9 77:2 122:14 124:10,13 144:13 146:1 <b>primary</b> 48:14 81:19,25 100:3 105:21 106:22,23 122:15 123:8,16 139:13 147:12 <b>principals</b> 62:16,18 <b>principles</b> 59:17 85:9 <b>prior</b> 12:13 13:14 18:19 29:1 35:8 45:8 53:14 58:4	110:19 117:4 128:1 133:13 153:23,24 <b>probably</b> 9:25 27:5 27:9,18 36:4 42:24 88:8 127:15 127:16 129:1 151:11 152:24 <b>problem</b> 33:23 36:3 38:2 96:9 111:9 150:24 153:6 154:23 155:8 <b>problematic</b> 130:22 142:10 <b>problems</b> 36:12 93:17 96:11 100:20 110:11 122:8 146:14 153:2,11 154:22 159:10,13 161:8 173:3 <b>procedure</b> 62:6 69:22 73:23 76:5 78:19 79:12 80:3 89:16 104:14,16 114:16 117:14 124:1 153:20 <b>procedures</b> 56:16 56:17 77:17 87:8 93:4 116:23 117:3 117:4 119:3 <b>proceeding</b> 28:25 <b>process</b> 63:13,19 64:3,11,20 65:6 66:17 97:18,20 141:20 168:14 <b>produced</b> 17:19 <b>product</b> 11:1,4,7,9 12:7,8 13:20,20 21:14 28:5 36:18 38:24 40:25 41:18 41:18 43:22,24 46:17 50:20,21,22 52:2 53:3,8,20 54:1,2,14,17,20 55:5,8 56:10 57:7	57:9 60:11 64:6 64:14 66:3,8,11 66:12 68:3,13,14 70:11,24 71:10,19 71:24 76:19 79:4 79:23 84:20 85:7 85:11 86:1,25 87:5,9,16 88:21 88:23 89:16,23 90:2 91:7,10,22 93:4 95:22 99:5 99:25 100:19 102:19 105:12,13 105:19 106:7 108:15 109:11 110:2,8 111:13 112:12 113:12 114:12,17 116:1 117:16,16 122:2,9 123:15 125:18,21 126:1,8,22 130:12 135:22 136:3,5,13 136:24 140:3 141:12 155:9 161:14,15 164:6,9 164:12 166:23 167:2,11 174:7 175:4,9,11 <b>products</b> 1:4 5:4 12:2 13:9,12,24 14:16 25:22 26:13 30:21 34:20 36:2 36:10 39:6 40:4 40:14,20 41:15 43:6 48:3 51:1 61:25 62:7,22 63:10 67:8 77:21 83:8,12 84:7,7,8,8 84:13,17,22,23,23 86:10 88:13,15 89:8 90:3,5 91:5 98:5 99:1 108:22 114:4 115:4 117:15 125:12 126:4,23 133:14 137:9 141:8
--	--	---	--	---

145:13 158:18,21 159:9,23 160:6,9 160:17,20,22 161:5 168:22 172:2 174:1,12 175:7,13 176:15 <b>professional</b> 45:13 45:18 131:6 <b>professor</b> 92:20 <b>program</b> 34:22 <b>prohibitions</b> 110:25 <b>prolapse</b> 15:22 16:5 35:22 41:5 43:7 44:2 45:4,6 45:10 46:9 50:19 51:20,24 54:5 58:4,7 75:17 76:1 103:12,18,22 104:1,5,14 106:14 111:25 116:23 122:11 123:19 125:20,21 126:15 126:25 136:10 144:25 159:22 160:6 161:24 164:13 173:25 176:21 <b>prolapses</b> 49:5 <b>prolene</b> 15:23 43:21,22,23,24 171:3 <b>proliferate</b> 5:4,5 6:4,5,6 6:6,8,8,18,18 8:1 10:14,19,19 11:24 11:24 12:14,14,25 13:1,4,4,12,16,17 13:24,24 17:14,14 18:8,9 21:12,12 21:21 24:9,9 25:21,22 26:13 27:13 29:12,12 30:22,22 31:11,11 32:19,20 33:10,11 36:15,15,22 37:5 37:23,23 38:14,14	38:16,16,25 39:5 39:6,19,20,24,24 40:3,10,10,14,14 44:3,3,23,24 48:2 51:18,18,23,23 52:8 53:1 56:14 56:14 58:5,5 59:21,21 62:5,6 66:25 67:1 70:11 70:16,18 71:7,19 71:24 72:23 73:11 73:11 75:18,18 80:16,17 82:4,4 82:10,10,17,17,22 82:22 84:2,2,12 84:12 86:9,10 88:12,13 98:24,25 99:9,9,17,17,23 99:23,25 100:1,8 100:8,14,14,17,22 101:5 103:4 108:21,22 111:21 111:21 112:2,2,6 112:7,13,13,14,15 112:20,20,23 113:2,7,8,11,11 113:13,13 114:1,1 114:9,9,18,18 115:12,12 116:20 116:20 118:15,15 119:5,5,9,9 121:8 121:24,25 122:4,6 128:20,20 130:4 131:3 135:17,18 139:19,19 140:5,5 153:22 159:25,25 161:12,12,17,17 165:10,11,22 166:17,17,21,21 168:5,5 170:16 172:16,16 173:4,4 173:18,18 <b>pronounce</b> 20:13 <b>proof</b> 70:6 <b>proper</b> 79:2 119:18 <b>properly</b> 86:11	88:15,22 159:9 161:10 <b>properties</b> 66:23 170:5 171:21 <b>proposed</b> 78:2 <b>propounded</b> 178:4 <b>prosima</b> 13:20,24 24:21 26:13 27:13 99:5,10,16 101:4 101:10,12,14,19 102:18,19,22 103:5,7 104:9,9 106:11 108:16 109:16 111:4,5,6 111:20,24 112:3,8 112:16,18,21 113:15 114:1,6 115:11 116:19 119:11 120:13,19 120:23 121:8 122:9,9 123:10 124:11 128:2,18 135:18 139:17 145:1,6,10 147:14 152:4 153:22 155:14 158:11 161:8,19,22 162:17 163:13,15 165:3,12,22 166:17,21 167:17 167:18 168:8 173:11,17,19 174:7 <b>prospective</b> 76:1 129:14 158:21 <b>prospectively</b> 130:2,6 <b>protocol</b> 80:1 <b>protocols</b> 53:25 96:23 <b>prove</b> 70:16,17 100:24 <b>proven</b> 100:23 <b>provide</b> 55:14 56:11 64:12 66:14 73:9 87:2 131:7	139:14 <b>provided</b> 7:25 8:6,8 8:23 17:10 22:3 22:12 23:4,20 24:12,16 29:13,21 31:2,13,20,23 44:20 45:9 55:18 55:19,21 63:22 65:10 74:1 82:15 92:7 102:18 108:4 108:8,11 110:14 144:2 161:4 163:18 <b>provides</b> 170:10 <b>providing</b> 53:12 170:9 <b>provision</b> 110:21 <b>public</b> 178:18 <b>publication</b> 33:19 34:4 37:9 104:7 <b>publications</b> 5:21 91:25 <b>publish</b> 81:4 <b>published</b> 41:11 44:8 73:1 75:24 81:17,21,24 103:13,24 105:25 107:5 122:12 170:24 <b>pubdental</b> 104:4 <b>pull</b> 31:19 32:3 120:8 <b>pulling</b> 114:24 <b>puncture</b> 121:13,16 137:25 <b>purchase</b> 50:24 89:18 <b>purchased</b> 175:3 <b>purchases</b> 51:1 <b>purporting</b> 132:10 <b>purposes</b> 58:25 66:7 71:15 131:14 <b>put</b> 11:3 20:23 22:19 23:8,17 24:3 29:19 54:1 57:22 60:14,21	63:9 70:25 79:6 85:11 86:2 113:17 126:25 140:13 151:22 155:9 156:14 157:10 162:17 163:9,21 163:23 <b>puts</b> 113:18 <b>putting</b> 158:13,15 <hr/> <b>Q</b> <hr/> <b>qualify</b> 148:14 <b>qualities</b> 66:6 118:19 <b>quality</b> 74:7 126:7 131:20 143:1 <b>quantification</b> 45:2 <b>quantified</b> 67:12 164:14 <b>quantify</b> 70:11 126:21 <b>quarter</b> 25:24 <b>question</b> 21:11,18 30:25 31:9,18 32:1,2 33:25 44:21 46:22 61:17 75:21 84:11 87:14 88:19 90:16 91:8 93:10 107:14,17 152:1 157:5 158:7 170:24 176:5 <b>questioning</b> 170:1 <b>questions</b> 28:12 34:7 47:25 91:24 98:11 99:15 168:3 169:2,23 174:9 175:22 176:3 178:4 <b>quickly</b> 152:9,11 <b>quit</b> 84:25 <b>quite</b> 12:11 18:2 27:4 123:17 128:9 <hr/> <b>R</b> <hr/> <b>r</b> 1:5 2:1 4:1 180:1 180:1
---	--	---	---	--

Bobby Lewis Shull, M.D.

Page 201

<b>rabbit</b> 43:11	125:15 126:22	58:18	7:23 8:3,10 19:1	39:6 41:14 51:17
<b>rabbits</b> 43:15	129:19 134:20	<b>reconstruction</b>	29:23 36:23 48:10	69:21 82:16 95:23
<b>rabiola</b> 25:10,10,16	135:22 142:18	16:13 49:24	73:3 92:13 107:8	101:18 108:15
120:20 121:20	143:10 148:25	170:25	131:3	109:15 114:8
<b>radiation</b> 109:20	149:11 150:13,24	<b>reconstructive</b>	<b>references</b> 7:8	119:5 152:16
<b>raised</b> 92:16	153:6,12,13,14	34:24 35:24 56:21	170:12	156:8 169:13
<b>raising</b> 47:24	176:24	58:21 59:17 62:16	<b>referencing</b> 37:4	179:9
<b>randomized</b> 79:12	<b>reason</b> 10:24 21:1,4	62:17 73:23 110:1	<b>referral</b> 138:13,15	<b>relating</b> 79:10
79:24 81:3 148:22	21:20 39:9 68:2	119:2 130:25	144:13	97:22 118:15
161:20 162:4,8	71:16 73:25	145:13 149:11	<b>referred</b> 46:3 82:9	158:24 170:4
<b>range</b> 35:25 36:1	110:12 126:10	155:22 165:25	85:10,13 86:21	171:14
<b>rat</b> 16:14 171:2	180:5,7,9,11,13	<b>record</b> 4:4,12,22	97:3 113:16	<b>relationship</b> 133:9
<b>rate</b> 48:4 68:18,19	180:15,17,19,21	5:17,20 11:10	123:21,24 138:21	134:19
69:23,25 70:6	180:23,25	16:23,25 17:3	143:22 144:10,15	<b>relationships</b> 132:5
74:22 76:10 86:22	<b>reasonable</b> 28:19	51:8,10,13 98:17	<b>referring</b> 26:7 37:2	<b>relatively</b> 139:23
105:19 125:1	28:23 48:18 57:18	98:20 103:9 108:8	52:1 124:2 133:16	<b>relied</b> 104:9
127:21,22 129:2,8	61:17 87:3,6	122:16 164:20,23	<b>refers</b> 38:7	<b>relieve</b> 113:8
148:3 156:23	88:21 97:12	177:7 179:7	<b>reflect</b> 11:15	<b>rely</b> 67:22
<b>rates</b> 114:2 115:4	145:17 146:20	<b>records</b> 39:2	<b>refresh</b> 121:22	<b>remain</b> 83:16
159:17	147:8,10 153:18	<b>recovery</b> 79:22	<b>refuse</b> 87:23,25	<b>remember</b> 11:9
<b>rationale</b> 100:22	<b>reasoning</b> 86:18	105:5 134:9,16	89:7	12:7,11 27:3
<b>reach</b> 73:8	<b>reasons</b> 78:17	166:4	<b>refuses</b> 89:5	38:24 42:21 48:5
<b>reaching</b> 30:20	94:25 129:13	<b>recreate</b> 48:24	<b>regard</b> 5:4 8:13	72:20 102:21
<b>reaction</b> 115:20	144:16 167:9	<b>recruit</b> 106:1	11:23 12:3 25:21	105:2 121:6,15,17
116:4 130:18	<b>recall</b> 19:23 104:25	148:11,12,13	25:21 111:21	122:3,4 128:14
136:19,21 137:2	107:8 121:5	152:10 154:16	<b>regarding</b> 8:23	129:24 130:1
138:1	129:22 164:9	<b>recruited</b> 78:18	11:1 13:16 54:16	133:4 136:14,17
<b>reactions</b> 111:15	<b>receive</b> 42:9 64:15	106:17,23 109:2	73:10,21 74:22	169:25 176:5
<b>read</b> 7:11,12,19,20	82:8 91:3	<b>recruiting</b> 117:10	85:3 101:14	<b>remind</b> 21:21
10:20,22,23 11:10	<b>received</b> 5:21 40:6	<b>recruitment</b> 154:10	108:21 139:15	<b>remote</b> 163:9
11:11,13 15:2,4	42:5,19 72:8	154:10,13	168:5	<b>removal</b> 77:7,9
19:1 22:19 30:10	82:12 112:10	<b>rectum</b> 37:5 125:6	<b>regardless</b> 91:14	122:17 135:16
33:25 92:11 94:4	<b>receiver</b> 97:13	<b>recurrence</b> 126:15	135:9 157:9	<b>remove</b> 41:14
97:23 98:2,4	<b>receiving</b> 42:22	146:13 152:23	<b>regional</b> 58:23	114:14 146:2
103:9 108:7	140:2	<b>recurrent</b> 123:19	<b>register</b> 175:16	<b>removed</b> 33:13
144:18 153:21	<b>recess</b> 17:2 51:12	127:8	<b>registrants</b> 175:2	41:22 83:23 84:2
163:12,15,16,16	98:19 164:22	<b>redde</b> 1:16 2:11	<b>registration</b> 110:24	84:6,14 156:5
163:17,22 164:2	<b>recognize</b> 96:4	<b>reduce</b> 46:14	<b>regular</b> 31:7	166:8
168:21,23 178:3	124:9 146:22	114:22 124:17	<b>regulations</b> 97:9,11	<b>removing</b> 169:18
<b>reading</b> 7:7 18:13	148:22 150:7	127:2 148:2	<b>regulatory</b> 63:19	176:4
18:19	<b>recognizes</b> 146:23	<b>reduced</b> 131:19,20	63:19 80:25	<b>reoperated</b> 123:19
<b>real</b> 57:20 78:12	<b>recommend</b> 71:17	172:21	<b>reinforce</b> 59:2	<b>reoperation</b> 68:2
155:21	<b>recommended</b> 62:6	<b>refamiliarized</b> 7:13	<b>reinforced</b> 139:4	126:10 127:21,22
<b>realistic</b> 48:25	167:18	<b>reference</b> 11:13	<b>relate</b> 102:22 104:9	129:2,8
<b>really</b> 57:18 59:5	<b>reconstruct</b> 58:9	73:1 85:23 164:15	140:14 147:2	<b>repair</b> 1:4 15:22
60:15 74:7 124:25	<b>reconstructing</b>	<b>referenced</b> 7:16,20	<b>related</b> 6:8,17 39:5	36:11 43:7 50:19



Bobby Lewis Shull, M.D.

Page 202

56:20 58:4,7 59:2 59:3 73:20 85:5,9 92:21 103:22 116:15,25 <b>repairs</b> 128:16 <b>repeat</b> 95:12 126:11,14 <b>replaced</b> 112:2 149:4 <b>replacing</b> 100:17 <b>report</b> 3:16 6:4,7 6:18 7:7,12,17,20 8:3 9:16 10:19,25 11:5,5,14,23 12:13 13:6,14,19 14:1 17:13 18:9 18:14,16,20,23,25 19:17 24:9,19,25 25:5,5 26:13,25 28:11,21 29:3,6,9 29:12,23 31:10,13 31:21 32:4,19 33:6,8,10,16 34:2 34:11,13,18 36:21 36:25 37:13,20,22 38:2 39:7,10,12 41:9,13 42:9,19 42:22 48:2,3 49:19 62:10,13 69:15 72:8,10,24 75:22 85:6,24 90:12 92:4,7,19 93:20 94:7,12,16 94:17 95:9 97:25 99:1,1,4,9,10 101:3,9,12,14,19 102:10,12,12 104:4,10 107:8,10 109:13 117:9 120:16 123:13 126:2 130:4 131:3 138:11 147:2 155:14 164:4 170:9,16 171:13 173:5 <b>reported</b> 34:25	35:3 37:6,7 43:16 59:8 69:14 71:22 73:4 76:16 106:18 108:20,24 113:25 115:3 117:8,11 123:7 129:9 132:25 149:9,11 159:7 173:21 <b>reporter</b> 1:20,21 4:16 43:23,25 162:7,11 179:3 <b>reporting</b> 38:2 49:21 56:5 77:20 158:18 <b>reports</b> 12:1,6,15 12:20,21 13:22 14:2 27:22,23 28:9,13 35:5,7 41:8 42:5 48:12 56:1,8,20,22 67:17 73:6 77:1 94:24 111:14 131:4,6 139:10 153:21 <b>represent</b> 56:15 116:20,21 <b>representation</b> 39:10 <b>representative</b> 91:7 91:23 <b>representatives</b> 174:14 <b>representing</b> 165:2 <b>represents</b> 14:11 <b>request</b> 5:18 19:20 20:6 22:18 23:25 24:11 25:2 32:10 35:2 72:6,9 87:1 92:12 144:1 146:4 160:13 167:20 <b>requested</b> 19:15 32:13 64:14 65:12 83:13 84:2 <b>requesting</b> 19:23 66:10,12 <b>require</b> 49:15 66:4	69:18 83:9 90:11 90:17 125:14 129:5 175:7 <b>required</b> 7:6 11:3 14:15 57:8 58:19 64:11 80:14,22 83:1,12 88:20 167:21 <b>requirement</b> 90:25 126:10 133:22 <b>requirements</b> 70:6 88:10 98:1 110:23 <b>requires</b> 64:24 90:6 116:14 119:19 135:22 <b>research</b> 31:1,19 32:3 40:23 43:13 108:10,18 <b>researching</b> 101:19 <b>reserve</b> 98:12 <b>reset</b> 132:8,12,14 132:17,19 133:2 133:15 <b>respect</b> 12:25 13:3 <b>respond</b> 65:14 76:25 135:1,4,8 158:7 <b>responded</b> 133:2 <b>response</b> 16:12 21:18 43:16 115:24 116:14 120:2,3 152:23 170:25 171:7,8 <b>responsibility</b> 30:12 167:12 <b>responsive</b> 5:14 <b>responsiveness</b> 30:23 <b>restraining</b> 88:6 <b>resulting</b> 114:25 <b>results</b> 30:4 72:14 81:5 124:23 <b>retropublic</b> 38:8 79:16,17 91:20 <b>review</b> 17:12 30:2 30:14 31:7 39:17	41:20 44:1 52:25 79:25 80:6,17 102:8,9,11 105:21 168:10 172:1 173:8 174:12,17 <b>reviewed</b> 7:23 14:20 30:22 31:8 44:22 93:13 166:16,20 168:17 174:20 <b>reviewing</b> 13:14,15 30:13 101:18 <b>revise</b> 11:14 72:5 102:11,11 <b>rheumatoid</b> 132:13 <b>rice</b> 2:3 <b>right</b> 6:3 7:10 10:1 15:20 18:5 20:15 34:8 37:17 50:12 69:3 86:15 87:15 88:14 99:14,21 102:6 103:6 107:9 112:20 119:11 152:12,24 155:10 158:2 <b>righty</b> 98:15 <b>rigid</b> 49:9,10,20 124:25 <b>rigor</b> 77:20 158:17 <b>risk</b> 52:6 59:16 62:15 78:5 90:24 119:1 135:10 141:11 142:12 145:6 151:1 <b>risks</b> 45:24,25 54:24 55:3 62:23 93:25 119:8,13 145:3 <b>robert</b> 5:9 <b>role</b> 15:14 <b>room</b> 145:21 <b>rough</b> 19:11 <b>roughly</b> 27:15 36:6 68:19 <b>rule</b> 3:16 6:7 101:13	<b>run</b> 8:12 10:8,16 <b>runs</b> 7:1 <hr/> <b>S</b> <hr/> <b>s</b> 1:6 2:1 3:9 4:1 <b>sacrocolpopexy</b> 35:23 47:11 50:11 73:16,19 145:14 176:11,12 <b>sacrospinous</b> 135:20 <b>safe</b> 58:21,22 60:10 60:13 61:14 83:2 83:3,16,21,22 84:3,13 <b>safely</b> 62:23 <b>safer</b> 161:18 <b>safety</b> 79:3 84:19 89:4 128:2 139:16 147:14 151:25 152:4 160:22 161:6 <b>sale</b> 86:25 105:17 <b>sales</b> 91:4,15 92:1 174:14 <b>saline</b> 79:19 <b>sample</b> 42:10 <b>samples</b> 175:9 <b>satisfaction</b> 70:8 126:7 <b>satisfied</b> 70:3,9 <b>saw</b> 19:21 34:21 36:3 38:14 91:5 92:13 <b>sayer</b> 123:7,7 <b>saying</b> 56:17 74:16 77:19 124:6 138:5 138:8 142:23,25 151:16 156:15,16 156:17 162:13 <b>says</b> 10:11,19,24 11:11,11 88:19 130:20 131:11 136:16,18 144:21 160:5 <b>scale</b> 61:2 136:2
---	--	---	---	---

Bobby Lewis Shull, M.D.

Page 203

<b>scar</b> 68:12 120:6,6 130:14 137:24 138:2 <b>scarification</b> 115:15 <b>scarring</b> 115:21 116:4 137:19,22 <b>schedule</b> 169:14 <b>scientific</b> 11:8 12:7 14:5 30:14 41:9 41:12 47:1 51:22 51:25 53:25 54:24 77:20 79:7 81:7,9 91:13 111:23 147:13 158:17 174:22 <b>scott</b> 23:21 169:4 169:19 176:4,7 <b>screen</b> 17:9 <b>screening</b> 168:13 <b>seal</b> 179:14 <b>search</b> 39:4,4 97:21 <b>second</b> 6:16 16:4 61:12 74:5 116:18 119:22 157:22 <b>section</b> 92:4 172:5 <b>sedation</b> 166:13 <b>see</b> 9:1 19:5 21:7 24:3 25:7,16 30:3 40:2 53:23 60:9 60:23 61:14,21,22 67:20,20 71:3 72:25 78:17,18 79:20 82:15 92:13 96:4,10 107:9 109:9 111:3,14 113:6 122:7 131:13 138:16,24 139:2,3,6,8,9,12 143:3 151:15,16 154:25 155:17 160:25 163:9 166:7 170:21 171:14 172:19 <b>seeing</b> 35:12 142:14 169:4	<b>seek</b> 133:17 <b>seen</b> 5:10 33:11,17 34:3,17 35:3,13 35:20 36:8 45:7 56:8 68:16 70:15 70:17 71:5,6,8,15 74:2 95:1 96:6 100:24 113:24 120:12,23 130:24 143:24 144:4,9,23 150:18 154:20 156:13 169:9 173:13 <b>segment</b> 175:15 <b>select</b> 58:14 168:14 <b>selected</b> 20:19 <b>selection</b> 76:6 86:12 89:6 141:14 141:20 152:14 154:7 172:8 <b>selective</b> 133:11 <b>selfselect</b> 138:21,23 <b>sell</b> 87:25 89:12,13 174:11 <b>selling</b> 84:25 89:21 91:15,16 <b>sense</b> 97:13 115:11 129:7 137:8 <b>sensitivity</b> 118:24 <b>sent</b> 15:16,17 17:12 19:22 20:7,9 22:15,15,17 32:5 41:19 42:1 71:22 72:3 101:24 102:1 102:3 144:1 168:15 <b>separate</b> 88:4 99:4 102:18,18 109:16 112:6 165:8,11 170:19 <b>separated</b> 112:17 <b>separately</b> 102:22 107:24 <b>september</b> 16:7 <b>sequelae</b> 86:13 <b>sequence</b> 112:18	<b>sequentially</b> 77:24 <b>series</b> 103:8 114:9 <b>seriously</b> 82:11 <b>served</b> 65:18 <b>services</b> 110:15 <b>set</b> 48:22 55:11 88:20 129:14 130:13 145:17 153:7 179:6,13 <b>sets</b> 95:23 <b>setting</b> 159:11,14 160:21 <b>seven</b> 76:10,21 86:22 <b>severe</b> 130:23 <b>severity</b> 75:1 <b>sew</b> 60:21 <b>sexual</b> 58:2,12 74:8 118:13 130:6 132:5 159:20 <b>shared</b> 147:4 <b>sheep</b> 117:24 <b>sheet</b> 101:11,18 165:5 178:5 <b>shes</b> 81:25 <b>short</b> 164:19 <b>shorter</b> 112:24 <b>shorthand</b> 179:3 <b>show</b> 5:7 79:2 101:2 128:17,23 128:24 142:10 162:5,9 175:12 <b>showed</b> 30:3 128:21 162:1,2 <b>shown</b> 137:13 154:2 175:20 <b>shows</b> 48:4 150:2 <b>shrinkage</b> 67:19,20 67:21,24 70:11 171:15 <b>shrinking</b> 159:7 <b>shrinks</b> 120:7 <b>shull</b> 1:10 3:3,12,13 3:16,17 4:11,18 4:24,25 5:13 8:8 17:5 31:18 98:17	98:23 101:14 104:10 165:1 168:3 177:7 178:8 179:5 <b>side</b> 47:4 50:7 115:6,6 165:19 <b>sides</b> 47:21,22 <b>significance</b> 170:6 <b>significant</b> 24:4 56:15,18 57:10,15 116:21,22 131:15 <b>signing</b> 35:8 <b>silimed</b> 109:19,21 110:2,5,16 128:6 128:9,13 <b>similar</b> 14:4 24:25 64:15 69:12,16 99:11 114:5 115:17 123:2 129:8 137:8 148:17 161:13 173:23 174:7 <b>similarities</b> 155:21 <b>similarity</b> 66:11 <b>similarly</b> 173:19 <b>simply</b> 111:13 114:16 <b>sir</b> 5:12,16,19 6:2 6:10,19,20,25 7:3 7:14,18 8:18,20 8:22,25 9:6,23 10:3 11:25 13:2 13:18,21 14:14,18 15:19 16:3,11,18 16:22 17:7,21 18:1,6,11,17 19:7 19:19 20:4,13,21 20:24 21:3 22:1 22:13,20,25 23:6 23:9,18 24:1,5,10 24:13,17,20 25:1 25:14,16 26:5,9 26:15,22,24 27:16 28:3,8 29:5,10 31:6 32:21 33:5,9 33:15 34:18 35:6	35:15 36:7,13,22 37:1,1,15,18,21 38:12,20 39:21 40:18 41:4,6,16 41:21 43:13 45:11 45:15,20 48:6,8 50:13,23 51:19 52:12 59:19 63:3 63:14,17 65:20,23 65:23 66:24 67:2 67:5 69:1,2 79:5 80:7,9,11,14,19 81:2,6,9 82:7,19 91:5 92:3,10 93:16,22 95:2 96:18 99:3,13 101:1,15,16,21 102:7,15,16,20 104:11 107:3,19 107:22 108:14,23 111:18 112:4 117:1,15 118:17 118:23 119:12 120:14,21 122:1 122:10 128:21 131:2 135:19 138:8 139:20 140:6,10 143:19 145:8,11 156:17 160:1,10 161:2,7 161:18 163:14 167:5,8,15 176:6 <b>sit</b> 42:21 141:25 157:4 <b>site</b> 54:5 121:16 <b>sites</b> 54:7 121:13 <b>sitting</b> 82:14 <b>situation</b> 88:3 <b>six</b> 22:8 56:2 123:23 127:1,2,4 153:11,12,14 166:4 <b>size</b> 42:14 58:10 115:16 <b>sizes</b> 132:23 <b>skill</b> 76:8 88:20
---	--	--	--	--

Bobby Lewis Shull, M.D.

Page 204

146:8,8 160:1,3,4 <b>skilled</b> 47:10,12,15 86:20 150:23,25 <b>skills</b> 34:23 87:11 <b>skin</b> 53:5,5 57:7,17 166:8 <b>skips</b> 22:22 <b>slack</b> 105:24 106:22 123:8 <b>sling</b> 41:24 61:16 61:16 68:1,3,5 69:9,17,18 79:17 118:1 163:1 <b>slings</b> 35:21 50:14 50:15,21 61:18 67:25 91:20 171:19 176:15 <b>smaller</b> 68:12 113:4 114:24 115:14 <b>smoke</b> 141:3 <b>sneezing</b> 70:4 <b>societies</b> 45:13,18 45:22,23 <b>soft</b> 164:9 <b>sold</b> 84:8 105:13 <b>solicited</b> 54:12 <b>somebody</b> 137:16 144:3,6 145:22 152:19,22 153:17 155:1,5 166:12 <b>someones</b> 134:21 <b>sophisticated</b> 119:19 135:3 137:18 160:2 <b>sorry</b> 51:3 90:15 94:13,18 95:12 107:3,4 148:3 152:2 156:11 157:1 162:7,12 <b>sort</b> 105:1 125:21 131:18 154:5 175:6 <b>sought</b> 143:11,13 <b>sound</b> 59:17 62:15 62:17 119:2	<b>sounds</b> 121:6,9 134:22 <b>southern</b> 1:1 4:10 <b>space</b> 60:13 79:17 119:18 155:17 163:8 <b>spaces</b> 52:18,19 61:19 104:20 105:4 113:23 119:20,22,23,24 120:4 158:14 <b>speaking</b> 70:7 170:15 <b>special</b> 52:14,21 149:10 <b>specialist</b> 45:16 <b>specialists</b> 45:21 <b>specialize</b> 45:13 <b>specific</b> 39:3,15 52:7 59:16 60:2 62:15 71:25 76:24 85:23 97:5,6 110:11 119:1,8,13 130:6 134:23 136:14 146:6 150:1,7 165:17,20 169:13 <b>specifically</b> 15:3 23:25 25:8 26:15 32:15 36:22 39:11 61:23 72:15 104:8 124:2 126:5 133:12 161:5 164:2,14 170:12 <b>specifics</b> 27:8 <b>specimens</b> 72:2 <b>spectrum</b> 36:10 150:20 <b>spend</b> 134:3 <b>spent</b> 9:9 18:13 27:24 101:18 165:2,7,10 <b>spiral</b> 131:25 133:8 133:16 <b>spoiled</b> 132:1 <b>spoke</b> 7:8 73:3	<b>spoken</b> 28:22 123:21 <b>sponsored</b> 44:8 175:1 <b>spontaneously</b> 32:13 <b>spot</b> 61:8 <b>spots</b> 60:10 104:23 <b>spotting</b> 166:7 <b>spouse</b> 134:19 151:19 <b>stable</b> 131:21 <b>stack</b> 32:24 <b>stage</b> 45:6 164:16 <b>stages</b> 44:2,23 56:5 <b>stainless</b> 116:12 <b>standalone</b> 111:12 <b>standard</b> 42:25 43:8 59:22 62:5 62:18 65:24 66:17 66:21 83:2 106:4 109:3 <b>standardization</b> 50:25 <b>standards</b> 97:9 <b>standpoint</b> 28:19 49:11 63:7,9 67:7 67:11 97:6 121:3 136:1 146:5 162:25 172:17,19 172:24 <b>stanford</b> 48:3 <b>start</b> 35:12 77:12 121:8 152:1 153:18 <b>started</b> 54:2 107:15 <b>state</b> 4:22 6:21 33:10 174:24 179:4 <b>stated</b> 12:9 <b>statement</b> 19:18 29:8 45:14 48:7 95:4 99:12 101:20 115:18 160:24 162:13 <b>states</b> 1:1 4:9 10:13	<b>stating</b> 48:3 <b>statistic</b> 48:9 <b>statistical</b> 148:16 149:10 <b>stays</b> 164:9 <b>steel</b> 116:12 <b>stent</b> 128:6 <b>step</b> 106:9 <b>sterile</b> 85:13,15 159:2,3,5 <b>sterilized</b> 118:18 <b>steve</b> 4:17 <b>steven</b> 1:20 179:3 179:18 <b>stimulate</b> 116:3 <b>stimuli</b> 124:16 <b>stitching</b> 104:21 <b>stogel</b> 1:20 4:17 179:3,18 <b>stop</b> 158:5 <b>story</b> 73:23 <b>straighten</b> 163:11 <b>straining</b> 70:4 <b>straps</b> 104:18 105:1 105:4 113:17,17 119:1,14,18 120:5 162:16,17 <b>strategy</b> 151:13 <b>street</b> 2:5,13 <b>strengths</b> 122:22 <b>stretched</b> 67:10 <b>strict</b> 153:19 <b>strictly</b> 124:24 <b>stringent</b> 70:5 <b>structure</b> 114:17 114:18 136:6 <b>structures</b> 57:21 114:24,25 135:23 135:25 <b>stub</b> 3:13,17 6:15 10:9,15,17,17 101:24 <b>studied</b> 21:5,13,15 21:19 40:23 66:22 <b>studies</b> 21:13 43:12 48:4 67:6,19,20	72:12 74:6,8 79:2 81:3 87:4 128:1,5 128:8 <b>study</b> 40:20,23,25 76:2 78:24 79:1,7 86:19 97:5 104:1 106:1,8,10,12,16 123:10 124:6 129:14 140:8 154:18 163:24 <b>subgroup</b> 58:14 <b>subject</b> 9:15 110:21 112:16 <b>subjective</b> 67:13 126:7 <b>submit</b> 72:9 <b>submitted</b> 6:5 18:8 26:25 33:18 34:3 34:16,19 42:10,13 64:1 66:1 80:12 81:7,16 84:18 <b>subpoena</b> 5:14 24:15 <b>subscribe</b> 31:6 <b>subscribed</b> 178:14 <b>subsequent</b> 106:20 112:15 <b>subsequently</b> 54:9 <b>subset</b> 34:23 71:14 <b>subspecialists</b> 138:12 <b>substance</b> 178:4 <b>substantial</b> 99:22 100:13 <b>substantially</b> 66:13 110:18 <b>substantiating</b> 83:12 <b>substantive</b> 10:2 <b>subtle</b> 155:13,16 <b>suburethral</b> 35:21 50:14,21 61:16 <b>success</b> 16:4 48:4 105:18 106:4 124:23,25 125:1 125:25
---	--	--	--	---

Bobby Lewis Shull, M.D.

Page 205

<b>successful</b> 32:23	154:22	146:7 175:7	98:24 100:7	163:4
<b>successfully</b> 88:24	<b>surgeries</b> 36:10	<b>suspect</b> 71:1 88:8	106:12 112:5	<b>ten</b> 76:17
<b>sue</b> 151:16	45:10 126:8 134:6	<b>suture</b> 58:16 166:7	132:24 165:3,7	<b>tender</b> 130:14
<b>suggesting</b> 43:8	134:7	<b>sutured</b> 56:25	<b>talks</b> 10:17	<b>tenderness</b> 172:22
133:13 143:4	<b>surgery</b> 16:5 32:23	<b>sutures</b> 166:1,2,15	<b>tape</b> 3:15 36:23	<b>tension</b> 68:8 70:25
151:5	32:25 34:24 35:24	<b>swear</b> 4:17	37:3,13 38:6,8,10	162:14,17 163:10
<b>suggests</b> 143:5	39:20,25 43:3	<b>sworn</b> 4:19 178:14	<b>taught</b> 40:15	<b>tensionfree</b> 3:14
<b>suite</b> 1:17 2:5,13	46:5,10,12 47:8,8	179:6	155:19	36:23 37:3,13
<b>summarize</b> 11:22	47:17 48:24 49:19	<b>symptomatic</b> 45:1	<b>teach</b> 16:21 156:1	38:6,8 103:22
31:12 140:7	54:5 55:3 56:21	45:3	<b>teacher</b> 15:15	<b>tenyear</b> 36:6,8
<b>summarized</b> 29:8	56:22 57:5 58:3	<b>symptoms</b> 69:11	155:25	<b>term</b> 55:24 57:6
32:19 33:4,7	58:20,22 60:4,14	71:4	<b>teaching</b> 15:1 40:15	123:21,24 132:1
<b>summarizing</b> 34:16	60:17 68:6,6 69:5	<b>synthetic</b> 46:17	53:13 91:7	135:23 136:15
<b>summary</b> 33:17	75:7,18 76:9,15	47:16 57:1,2,6	<b>technical</b> 38:7 54:7	137:11
34:2,11,14	77:4,8,9,11 78:11	69:17 85:7,11	54:14 60:18 66:4	<b>terms</b> 45:5 47:7
<b>supplied</b> 10:5	85:14,15,18,21	86:1 110:1 117:8	66:6 76:4 87:11	73:19 85:13 90:22
<b>supply</b> 60:5,6	93:5 96:1,13 97:6	118:1,7 171:4	136:1,7 146:8	114:21 116:4
<b>support</b> 46:10 54:6	103:11,18 104:1,5	176:12	<b>technically</b> 47:10	123:4 139:23
54:6 103:12,19,23	104:24 106:3,5,13	<b>system</b> 1:4 49:21	50:6 62:1 77:12	<b>test</b> 67:13
104:2,13 105:9,22	109:3,16 110:1,8	65:9 90:2 100:5	77:18 145:23	<b>tested</b> 69:13 159:9
106:6,14 109:8,14	116:14 117:22	113:20	150:23 152:16	<b>testicle</b> 146:2
109:17,18 110:9	120:14 122:11,17	<b>systematic</b> 52:4	<b>technique</b> 38:4	<b>testified</b> 4:19 65:21
110:10 111:5,12	123:2,11,20 124:3	<b>systematically</b>	52:21 55:22 72:25	<b>testifying</b> 25:15
111:17 122:14	124:18 125:15,15	160:21	75:25 92:21 139:1	<b>testimony</b> 13:14
124:8,12,18,19	126:12,14,18		154:22,23 156:8	23:23 25:21 29:3
127:13 128:3	127:3,8 129:16,17	<b>T</b>	165:17,21	65:22 87:21 179:7
158:15	129:18 130:7,10	<b>t</b> 3:9 180:1	<b>techniques</b> 53:12	<b>testing</b> 21:22,24
<b>supporting</b> 11:15	130:25 133:13	<b>table</b> 82:14 149:11	53:13 96:7	67:3 77:20 80:16
51:23 92:5 111:24	134:8,15 135:7,10	<b>take</b> 5:3 51:4 59:6	<b>technologies</b> 4:5	95:6,15,22 96:20
<b>supposed</b> 89:20	135:11,16 138:19	65:6 84:24 94:10	<b>tecum</b> 5:15,18	96:22,23 158:18
<b>sure</b> 8:15 10:15	139:13 140:15,16	94:19 150:3 153:5	24:15	166:16,21
15:6 21:8 37:7	140:16,17 142:24	154:10,11,11,13	<b>tell</b> 9:9 12:1,4 19:8	<b>texas</b> 1:18,21 2:14
42:23 80:21 87:19	144:1,25 145:2,14	164:19	21:9 40:9 44:22	4:8 179:4
91:1 94:22 95:13	146:1 149:12,13	<b>taken</b> 20:15 22:7	66:17 86:15 87:15	<b>text</b> 131:7
121:21 128:7	149:17,21 150:1	23:21 24:7 25:3	87:22 99:18	<b>thank</b> 43:25 51:9
164:7	152:19,21 153:23	30:14 107:23	119:13 121:21	170:22 177:5
<b>surface</b> 115:13	153:24 155:22	163:21	132:11 140:1	<b>thats</b> 5:15 12:16
136:3 167:11	161:21 165:25	<b>takes</b> 152:23	145:16 147:4	17:6,10 18:3,21
<b>surgeon</b> 59:20,22	<b>surgical</b> 41:7 42:6	<b>talk</b> 12:24 91:17	148:8 150:8	19:3 20:10,16
59:25 60:15 62:5	49:7 56:16,17	150:5 169:12	151:21 152:3	21:19 22:5,11
95:5,13,18,23	59:17 62:16,17	<b>talked</b> 25:18 66:16	158:5,9,17 159:12	24:7 25:4 27:3,5
154:17 155:7,12	85:9 93:6 96:5,7	94:4 96:21 117:2	160:17 167:16	28:3,8,19,21
155:16 167:13	103:22 104:14,16	118:3 122:7	<b>telling</b> 36:1	29:16,18 32:24
<b>surgeons</b> 53:11,19	116:22 117:3,14	124:15	<b>tells</b> 154:16	33:1,21 34:5 37:7
55:13,18 56:12	119:2 128:16	<b>talking</b> 10:15,24	<b>template</b> 28:10	37:21 38:12 43:8
61:19 68:18 87:11	134:11 138:3	36:25 60:16 85:4	<b>temporarily</b> 116:17	46:21 47:5 48:15

Bobby Lewis Shull, M.D.

Page 206

49:20 50:2 61:11 62:2 63:24 65:12 65:16 66:1 71:20 73:14 74:4,10 76:14,22 79:18 86:16 87:6,10,16 88:8,18,25 89:1 91:8,12 93:10 94:3,22 95:3 96:1 96:13,25 98:10,14 99:10,20 100:3,23 101:4 102:6 106:8 106:13 107:20 108:17,24 113:10 113:10 115:19 116:8 118:14,17 118:18 119:4,12 120:8 122:14,23 123:13 124:20 125:9,22 128:19 129:9 132:2,18,21 132:21 133:11 134:5,16 136:2 137:1,7,17 139:18 139:20 141:14,14 144:13 145:22 146:20 147:11,11 148:6 149:13 150:13,14,16 151:4,18 152:25 153:16 154:3,14 155:13,16 156:1 157:13,24 160:19 162:1,1 166:14 167:2,6 169:11,22 173:10 174:5 175:6 177:4 <b>theoretically</b> 114:20 161:18 <b>therapy</b> 96:6 109:20 133:24 <b>theres</b> 10:18 17:17 20:16,16 21:5 41:9 45:16 47:14 47:19 64:16 67:14 67:21 71:14,16	76:18 84:17 88:18 88:20 92:1,2,4 99:10 103:9,16 107:4,7 108:12 109:24 112:25 116:16 124:2,3 127:20 131:16,22 132:3 133:6 134:4 134:11 138:10 141:10 145:3 147:22 150:20,23 153:15 155:12 157:3 159:3 160:14 <b>theyll</b> 176:11 <b>theyre</b> 8:25 66:10 69:23 71:9 78:15 78:16 84:20 87:24 89:21 91:14,16 102:20 108:2 112:9,9 113:12 115:10 118:6 124:1,10,12 129:1 129:2 131:13,17 140:24 143:14,14 146:9,12 155:17 173:23 176:15 <b>theyve</b> 35:2 40:9 70:15 132:19 143:18 144:18 <b>thing</b> 25:7 47:9 54:25 55:4 74:4,5 87:6 88:21 108:23 110:3 113:10 119:21,22 123:25 125:23,24 129:14 132:9 141:16 142:22 149:15 150:16 155:13 <b>things</b> 14:4 15:13 15:15 24:14 32:14 35:23 37:8 47:6 73:15 74:22 95:19 115:1,17 116:1 118:5,24 122:10 122:15,16 124:21	125:12 130:15 133:9,21 134:10 134:20 135:1 137:13 141:1 142:4,6,9 144:14 146:3 147:8,10 153:15 154:15,18 158:12 175:20 <b>think</b> 6:10 10:14,23 12:5,14,16,21 13:18 18:19,21 19:7 26:22,24 27:8 28:8 31:16 31:17,23 32:24 34:5,6 38:13 42:18 43:3,14 44:18,25 46:20,24 47:6,19 50:17 61:4,7,13 62:9 64:7,9 67:15 69:19 70:14,24 71:11 72:8 73:25 74:10 75:7,9,11 75:13 76:23 77:10 77:14,22 88:2,4 88:18 89:13 94:9 96:14 103:10 107:17,22 114:5 116:12,13 119:16 123:25 127:9,10 128:25 130:9,20 134:25 136:20 143:5 145:6 146:22 147:24 151:5,7 154:22 156:8,12 157:7 158:12 160:14 165:20 166:22 167:21 168:21 170:7,19 174:17 176:21 <b>third</b> 6:16 126:9 131:22 <b>thompson</b> 2:4 3:5 4:13,13 5:17 7:8 8:7,11,13 9:6,9	10:12 12:23 13:5 13:10 14:10,17,23 17:15 26:3,6,9,18 26:23 28:12,15,22 29:15,22 30:6 31:5,15,22 32:7 33:20,24 34:1,6 37:24 38:5,18 40:22 43:2,20 44:4,7,11,13 46:2 47:23 51:6 52:15 52:24 53:16 54:3 54:21 57:12,14 59:24 62:8 64:8 64:21 65:2 66:2 66:19 68:23 74:18 75:12 80:10 81:1 82:18 83:6,18,24 84:5,15 86:17 87:18 88:1,16 89:9,24 90:9,20 91:11 93:1 94:2 97:1 98:11,15 99:24 102:6 103:4 105:20 111:7 115:22 116:10 117:18 120:25 134:24 136:22 137:21 140:11 143:20 144:11 147:17 156:10,21 156:25 157:2,7,11 157:14,17,21,25 158:2 162:23 166:18 168:2 169:8,23 171:25 173:3,24 174:4 175:21 176:9 <b>thought</b> 19:16 24:17,22 108:1 147:18 150:20 163:20,23 <b>thoughts</b> 18:22 46:16 <b>thousand</b> 27:9,10 <b>thousands</b> 155:20	<b>three</b> 15:4,8,20 23:23 27:5,8,23 32:17,18,25 33:7 34:7 49:16,17 56:2 76:9 86:22 113:6 125:14 129:24 131:12 132:24 157:19,21 170:23 <b>threepage</b> 6:14 <b>threeyear</b> 56:4 76:1 <b>thumb</b> 8:8,9 103:2 <b>tie</b> 146:2 <b>tight</b> 172:21 <b>tighter</b> 71:1 <b>tightly</b> 67:10 68:5 <b>time</b> 4:7 7:5 9:24 17:1,4 18:12 21:11 26:1,3,15 27:24 28:1 36:3 46:13 51:11,14,21 54:10 55:14 56:9 56:11 59:7 69:2 69:21,24 70:13 73:2,14,24 74:2 75:15,22 78:15 79:14 98:17,21 101:11,17,18 104:23 105:5 111:22 119:25 120:22 134:3,4,5 134:9,11 145:24 145:25 146:7,22 147:25 148:2,5,5 149:6,16 150:9 153:7 157:13 162:24 164:21,24 165:1,3,4,4,5,7,10 165:11,19 166:3 177:8 <b>timeframe</b> 72:13 72:21 <b>timeframes</b> 112:6 112:10 <b>timeline</b> 112:12 <b>timely</b> 10:4
---	---	---	--	--



Bobby Lewis Shull, M.D.

Page 207

<b>times</b> 120:15 134:15 163:1	117:13 128:15 130:24 161:21	161:20 162:5,8	13:11 22:8 23:10 27:22 38:23 40:3	<b>unique</b> 52:13,17,21 86:11 89:6
<b>tiny</b> 150:23	<b>train</b> 86:11	<b>trials</b> 75:14 77:1	40:6,8 58:7,8 79:9	<b>united</b> 1:1 4:9
<b>tissue</b> 42:14 45:9	<b>trained</b> 89:5,8	79:24 81:4,5	79:24 81:3 88:4	106:21
53:4 56:19 57:17	96:16	84:19 95:22 96:17	96:21 122:10	<b>universally</b> 126:11
57:21 59:2 60:3,4	<b>training</b> 40:13,14	158:21	123:12,20,22	<b>universe</b> 14:19
60:4,22 69:6,8	87:1,5,23 91:3	<b>tried</b> 27:11 104:25	125:12,14 130:3	<b>university</b> 81:12,20
72:7 76:15,17	167:17	130:5 156:9,11	131:4 134:14	131:4 133:1
104:20 105:10	<b>transaction</b> 160:14	<b>trigger</b> 130:14	146:7,9 153:8	<b>unknown</b> 54:14
118:20 120:6	<b>transcript</b> 20:11,22	<b>trocac</b> 38:9 56:23	155:11 157:17,18	158:13
137:9 146:18	22:4 23:4,13,14	56:25 57:11,19,23	157:22 174:17	<b>unsatisfactory</b>
165:15 166:3	24:6	60:11,19 61:17,23	176:10,16	49:11
167:10	<b>transcription</b> 178:3	104:17 113:12	<b>type</b> 33:16 34:2	<b>untreated</b> 125:13
<b>tissues</b> 67:10	<b>transcripts</b> 20:6,7	114:7 120:2	39:20 42:6 51:25	125:19
114:10	<b>translate</b> 95:5,14	<b>trocacbased</b> 86:13	104:16 109:16	<b>updated</b> 5:19,24
<b>titled</b> 16:12 37:13	<b>transpired</b> 78:17	174:5	114:21 115:24	101:10
<b>titles</b> 171:12	<b>transpires</b> 135:13	<b>trocars</b> 52:3,8,13	123:14 143:22	<b>urinary</b> 37:3 41:2
<b>today</b> 5:3,14 9:5	<b>transportation</b>	52:16,17 53:3	<b>types</b> 56:19	68:25 69:5 80:3,4
12:24 13:22 15:3	134:2	54:8 57:8,13 59:9		<b>urogynecological</b>
26:8 28:2 39:1	<b>transvaginal</b> 35:24	59:16,21 60:1,2	<b>U</b>	37:17 45:23
42:21 70:17	43:1,7 46:1 50:19	62:14 104:20	<b>u</b> 1:6	103:24
117:17 118:21	56:22 58:3 72:14	108:21 109:9	<b>ultimately</b> 106:11	<b>urogynecology</b>
125:15 142:17	75:25 86:19 95:24	110:4 119:7,10,11	162:18	103:17
152:20 155:4	171:18 173:19	119:15	<b>ultrasound</b> 67:15	<b>urologists</b> 61:19
163:19 165:8	177:1	<b>true</b> 73:23 77:14	<b>underdiagnosed</b>	<b>urology</b> 176:13,14
<b>today's</b> 4:6 7:6,9,11	<b>transvaginally</b>	94:3 95:3 113:10	152:18	176:21,23
<b>told</b> 17:5 25:9 27:7	56:21 128:18	127:15 160:19	<b>undergo</b> 78:19	<b>use</b> 31:12,21 32:4
38:13 96:18	165:25 173:25	168:8 169:11	79:13	36:11 39:24 41:23
145:13 160:8	176:20	173:11 174:4,6	<b>understand</b> 5:5	43:1,6,22 44:23
165:11	<b>traumatized</b> 48:21	175:6 179:7	17:20 26:19 44:11	45:9,25 49:7,25
<b>tom</b> 59:9	<b>treat</b> 44:3,24 68:24	<b>truth</b> 87:7 96:10	44:15 46:11 52:25	50:14,20,21 51:2
<b>top</b> 6:15 15:21	125:7 127:5	97:25 116:13	53:17 83:1,4	52:17 53:15 54:17
21:10 32:24	148:10	124:10 150:22	90:16 93:25 95:2	54:20 55:5,8
101:23 115:7	<b>treated</b> 33:12 34:21	46:18 58:18 76:25	100:21 104:12,15	56:20,23 57:8,11
127:14	96:7 120:18 125:5	77:5 80:2 109:22	114:15 137:17	57:13,19,22 58:16
<b>total</b> 6:23,24 11:19	125:7,18 128:12	111:19 140:7	152:8 157:6	59:9,20,25 60:19
11:20,20 53:22	131:17 156:4	145:16 158:6,7	<b>understanding</b>	60:23 61:22 62:5
72:24 75:24	<b>treating</b> 25:11,19	162:11 163:10	54:25 105:18	62:7,21,23 66:4
102:13 165:4	120:16,18 138:22	<b>trying</b> 12:10 50:25	<b>understood</b> 104:19	70:8 72:14 73:15
<b>totality</b> 14:19	<b>treatment</b> 34:12,17	111:3 158:6	<b>undertake</b> 95:7,16	74:25 78:8 79:19
<b>totally</b> 116:3	68:24 75:25 129:6	175:19	<b>unfavorable</b> 54:16	79:20 83:4,17
<b>toxicology</b> 63:16	161:23 172:6	<b>turns</b> 57:18	168:20	84:4 85:3,8 86:15
<b>trademarked</b> 21:12	<b>trial</b> 53:8,10 54:24	<b>tv</b> 79:10,13 155:4	<b>unfolds</b> 73:23	87:16,22 88:15,20
<b>traditional</b> 56:16	55:2 79:13 80:2	<b>twice</b> 163:16	<b>unhappy</b> 141:12	88:22,23,24 89:8
56:16 57:5 106:3	147:13 151:22	<b>two</b> 5:4 9:11,18	<b>unintended</b> 142:10	89:23 90:11 91:3
116:22,24 117:3	152:4 153:9	12:5,14,20,21	151:8	91:7,22 93:24

Bobby Lewis Shull, M.D.

Page 208

96:8 104:17 105:3 105:5 108:21 109:15,20,24,25 112:21 114:6,7 115:25 117:8,15 119:11 125:2,5,7 126:3,22 127:22 128:17 132:1 139:1 141:6 145:13,18,18 153:20 158:19,24 159:15 160:2 164:3,5,8,10,17 165:17,21,25 166:1,15 167:17 167:18 172:1,3 175:12,16 176:12 176:15 177:1 <b>user</b> 97:11 <b>users</b> 44:17 54:1 123:9 140:19 <b>uses</b> 49:23 52:10 61:16 117:21 118:8 149:12 161:13 <b>usually</b> 42:10 50:22 58:14 <b>utah</b> 131:4 133:1 138:14 143:9 <b>uterosacral</b> 165:17	106:13,14 109:8 109:14,17,18,22 110:10 111:5,17 115:1,16 118:11 118:18,20 122:14 127:15 128:3,6 155:22 159:4,19 164:8 165:15 166:3,6,8,11 <b>vaginally</b> 47:13 136:10 <b>validate</b> 38:21 <b>variabilities</b> 148:18 <b>variable</b> 56:4 60:6 60:7 61:13 125:10 129:20 <b>variables</b> 87:10 129:15 140:14 146:7,9 148:24,25 152:7 154:1,6 <b>variety</b> 17:24 36:9 73:15 100:19 116:1 130:15 141:4 171:5 <b>various</b> 14:11 15:15 36:11 48:19 56:5,19 91:14 94:25 96:7 172:2 175:1 <b>vary</b> 14:4 <b>varying</b> 48:12 160:1,3 <b>vas</b> 146:3 <b>vascular</b> 60:5 <b>vascularized</b> 120:9 <b>vast</b> 15:14 <b>versus</b> 4:9 79:20 <b>vessels</b> 114:11 120:4 <b>video</b> 4:7 <b>videographer</b> 2:19 4:3,4,16 16:25 17:3 51:7,10,13 98:16,20 164:20 164:23 177:6 <b>videos</b> 92:2 175:5	175:10 <b>videotaped</b> 1:8 <b>virginia</b> 1:1 2:6 4:10 <b>visible</b> 41:24 <b>visit</b> 143:25 <b>vitae</b> 3:12 5:19 24:24 101:11 <b>vocabulary</b> 137:2 <b>voice</b> 18:22 51:3 63:6 162:11 <b>volume</b> 16:6 23:11 23:11,22 <b>vs</b> 1:8 <hr/> <b>W</b> <hr/> <b>w</b> 2:12 <b>wages</b> 134:9 <b>wait</b> 33:22 <b>walk</b> 13:22 14:2 51:16 99:8 <b>walking</b> 100:8 <b>wall</b> 16:13 57:25 86:7 118:11 159:1 159:1 171:1 <b>want</b> 13:15 46:5 50:6 71:8 75:6 78:2 124:20 133:1 142:21 146:19,25 146:25 147:9,9 148:2 149:21 151:16 163:3 <b>wanted</b> 9:13 10:5 11:1 87:1 92:13 94:20 107:25 123:13 149:8 167:20,22 <b>wanting</b> 47:25 124:16 <b>wants</b> 64:10 146:2 151:8 <b>warn</b> 136:20 <b>warned</b> 136:12 <b>warnings</b> 85:2,6 136:13 158:23 172:5,11	<b>warrant</b> 71:4 <b>wasnt</b> 25:12 26:2 74:1,13,15,19 80:14 84:10 90:4 91:6 130:7 140:13 140:21 147:3 152:17 155:5 164:14 168:16 <b>watch</b> 155:25 <b>water</b> 51:5 <b>way</b> 20:13 30:16 43:5 48:22 57:18 58:6 67:17 78:11 78:12 80:2 89:12 91:12 99:19,22 100:25 104:15,22 113:21 120:10 122:21 135:4 138:10 139:21 140:12 141:19 142:23 148:10,11 149:18 157:10,15 157:24 163:3 165:16 <b>ways</b> 67:23 174:17 176:10 <b>weaknesses</b> 122:22 <b>webb</b> 2:12 3:4,6 4:15,15,21,25 5:24 6:14 8:5,9,12 8:16 13:8,13 15:9 16:23 17:5,17 27:11 29:1,17,25 30:23,25 31:9,18 32:1,17 33:22,25 34:5,8,10 37:12 38:1,10 39:3 41:1 43:11 44:1,6,9,10 44:12,15 47:20 48:2 51:4,16 52:20 53:9,24 54:18 55:16 57:13 57:24 62:3,4,12 64:19,25 65:18 66:16,22 69:1 75:16 80:12 81:3	82:20 83:15,20 84:1,11 85:1 87:13,14,21 88:11 89:2,19 90:1,13 90:17 91:2 92:1 93:12 94:4 97:8 98:10,14,23 100:6 100:12 101:23 103:2,6,7 106:12 111:14 116:7,18 117:24 121:22 135:16 137:4 138:5 143:16,21 144:24 147:20 151:20,21 156:2,3 156:15,22 157:3 157:10,12,15,19 157:23 158:1,9 162:13 163:12 164:19 165:1 166:20 167:23 169:6,21 171:23 172:18 173:22 174:2,16 175:23 176:2 177:4 <b>weber</b> 130:4 <b>week</b> 13:11 25:3,6 25:8,18 26:24 27:25 68:6 152:20 <b>weekend</b> 163:17 <b>weeks</b> 166:4 <b>went</b> 19:13,24 33:3 61:23,24 98:25 171:8 <b>west</b> 1:1 2:6 4:10 <b>weve</b> 4:25 101:2 149:15,16 150:18 158:12 <b>whatnot</b> 15:1 91:25 102:5 120:9 134:16 136:24 <b>whats</b> 5:7 33:22 47:25 49:15 62:20 77:19 79:18 82:20 85:13 89:2 118:6 123:9 125:5 131:8
---	---	---	--	--

135:20 140:20 141:18 142:19 147:6 166:12 169:11 <b>whereof</b> 179:13 <b>white</b> 169:4,19 176:4,7 <b>whoever</b> 60:16 <b>whos</b> 69:13 <b>width</b> 42:12 <b>wife</b> 132:12 <b>window</b> 26:1 <b>wisconsin</b> 59:7 <b>withdrawn</b> 105:15 <b>witness</b> 4:17 43:24 51:9 90:15 158:4 162:8 167:23 177:5 179:5,8,13 <b>woman</b> 45:3 48:19 68:1 124:17 125:15 130:19 150:6 153:23,23 153:24 154:1 <b>womans</b> 52:22 <b>women</b> 13:12 33:14 36:9 38:14 40:2 46:8 48:20 52:4 58:14 59:10 69:8 70:23 74:4 76:9 78:19 79:13 96:10 109:20,25 110:8 123:11 124:11 126:12,13,17 127:23,24 128:10 128:12 129:3,9,15 130:9 131:7,11,16 131:22 132:19 133:14 138:17 139:11 141:10 143:17,22,24 146:14 148:13,23 148:24 149:25 153:25 156:6 164:6,8,10,13 <b>wont</b> 138:9 148:13 148:14	<b>word</b> 97:16 <b>wording</b> 112:1 167:19 <b>words</b> 127:4 <b>work</b> 6:6 7:2 10:14 11:22 12:19 14:12 14:16,25 26:1,12 26:14 27:12,13 39:22 40:8 46:12 69:3 78:22 107:25 132:14 134:16 145:24,25 146:6 146:16,16,18,18 149:5 163:8 175:9 176:17 <b>worked</b> 6:22 53:19 78:11 81:4 92:23 93:7 109:7 144:18 152:21 <b>working</b> 18:15 40:12 53:11,12 101:11 138:12 150:19 151:3 169:16 <b>works</b> 70:21 81:22 139:5 146:21 177:3 <b>world</b> 89:19 145:20 <b>worse</b> 151:2 <b>wouldnt</b> 24:23 37:10 42:2 71:12 85:11 95:25 117:23 130:18 139:24 154:23 <b>wound</b> 68:12 85:7 85:11 105:9 119:24 135:21 159:3 <b>wrap</b> 117:9 <b>wrinkling</b> 162:18 <b>written</b> 14:9 41:2 41:12 141:17 <b>wrong</b> 89:14 155:9	<b>xenograft</b> 46:18 118:6 171:4 <hr/> <b>Y</b> <b>yandell</b> 40:5 <b>yeah</b> 103:5 <b>year</b> 36:4 69:25 70:1 72:16 92:22 103:17 112:17 129:25 149:5 152:24 153:7,14 154:11,12 <b>years</b> 52:10 61:20 68:7,21 69:4 73:20 76:9,17 86:22 97:24 123:12,20,22 152:25 153:8 155:23,23 166:6 <b>yesterday</b> 7:9 9:6 9:10 165:8 <b>youd</b> 127:5 <b>youll</b> 14:13 146:12 148:12,14 <b>youre</b> 10:24 28:6 28:22 29:24 30:7 36:1,25 38:2 39:7 49:25 57:10 64:25 65:4 66:10 71:11 74:15 88:2,6 97:2 104:13 106:12 127:2 130:12 132:16,17,24 134:1,3 138:5 140:12 142:4,12 148:9 152:14 156:15,16 158:1 173:20 <b>youve</b> 5:25 6:11,17 8:16 10:7,8,17 13:3 14:20 15:20 17:5 25:8 26:17 27:13 34:3,17 35:3,3,4,13 36:8 36:23 43:11 68:21 93:17,20 101:17	120:22 121:23 131:1 134:22,25 152:13 154:20 157:14 158:2 <hr/> <b>Z</b> <b>zero</b> 156:15 <b>zierlein</b> 2:19 4:4 <b>zyczynski</b> 122:13 <hr/> <b>0</b> <b>00</b> 9:25 98:18,19 156:23 157:8 <b>000</b> 27:2,6,14,19 <b>01</b> 98:19,22 <b>02</b> 1:14 4:7 <hr/> <b>1</b> <b>1</b> 3:11 4:2 5:8 22:21 90:23 98:19,22 111:22 <b>10</b> 2:5 51:11,12,12 51:15 133:15 148:3,5 171:11 <b>100</b> 3:16 33:12 34:12 35:14 36:9 36:14 38:14 102:11 144:8 150:6 154:20 156:4,16 165:20 <b>101</b> 3:17 <b>102</b> 20:17 21:1,10 <b>11</b> 102:13 171:11 <b>114</b> 16:6 <b>12</b> 98:18,19 123:23 153:17 166:4 171:12 <b>1221</b> 2:13 <b>12cv00401</b> 1:7 <b>12md0237</b> 1:4 <b>13</b> 82:2 171:12 <b>135</b> 22:22 <b>136</b> 22:22 <b>137</b> 22:22 <b>138</b> 22:22 <b>14</b> 171:12 <b>15</b> 1:13 27:5,9	127:4 177:8,10 <b>150</b> 22:22 <b>15th</b> 4:6 <b>168</b> 3:5 <b>176</b> 3:6 <b>18</b> 11:11 48:20 140:23 <b>180</b> 102:9 148:14 148:15 <b>1800s</b> 58:21,24 <b>1850</b> 58:17 <b>18th</b> 22:8 179:14 <b>19</b> 127:1,2,5 <b>190</b> 11:13 19:2 <b>1900</b> 1:17 <b>1900s</b> 59:4 <b>1950</b> 73:17 <b>1975</b> 69:3 <b>1976</b> 110:19 <b>1996</b> 73:4 117:7,9 117:11 <b>1998</b> 110:15 <hr/> <b>2</b> <b>2</b> 1:4,7 3:12 5:23 6:1 23:11,11 51:14 69:4 90:23 164:21,22,22,25 <b>20</b> 19:12 27:6 48:20 76:13 86:22 133:7 147:25 148:2,4,8 148:13 162:2 178:15 <b>200</b> 148:13,13 <b>2000</b> 69:9 72:13 73:2 117:5,7 148:21 <b>2001</b> 69:4,10 <b>2004</b> 16:15 35:18 35:25 74:12 170:25 <b>2005</b> 15:25 35:25 72:13 73:2,7 <b>2007</b> 103:15 <b>2008</b> 103:15 <b>2009</b> 16:7 72:24
---	---	---	--	--

Bobby Lewis Shull, M.D.

Page 210

105:14 106:18 109:1 <b>2010</b> 37:17 75:24 103:20 104:3 122:12 <b>2011</b> 41:11 103:25 104:7 <b>2012</b> 20:15 22:8 23:2,22 41:11 105:17 <b>2015</b> 25:24 36:5 <b>2016</b> 1:13 4:6 7:2 10:19 11:11 102:1 179:14 <b>21</b> 140:23 <b>21st</b> 11:12,13 <b>22</b> 17:1,2 <b>22nd</b> 11:14,15 <b>2327</b> 1:4 <b>23rd</b> 7:1 11:17 103:15 104:7 <b>24</b> 153:18 <b>25</b> 19:12 27:18,20 69:4 <b>25301</b> 2:6 <b>25th</b> 23:22 <b>26</b> 3:16 6:7 27:2 51:11,12 101:13 <b>28</b> 27:2 110:19	<b>4</b> 3:4,11,14 37:11 37:12 118:25 164:24 <b>40</b> 133:6,13,15 <b>403</b> 2:5 <b>43</b> 51:12,15 <b>44</b> 94:15 <b>45</b> 11:16 102:14 <b>4500</b> 2:13 <b>49</b> 164:21,22 <hr/> <b>5</b> <b>5</b> 3:12,16 6:24 10:10,18 11:21 35:18 74:12 100:11 101:3,13 127:5 128:1 <b>50</b> 11:12,20 18:18 27:14 101:25 102:14 148:4 <b>504</b> 23:14 <b>505</b> 23:14 <b>506</b> 23:15 <b>507</b> 23:15 <b>510</b> 64:5,9,11 65:8 83:11 98:4 110:16 112:10 <b>515</b> 1:17 <b>522</b> 154:15 <b>530</b> 11:19 <b>56</b> 164:22,25 <b>5th</b> 20:15 110:15 <hr/> <b>6</b> <b>6</b> 3:13,17 23:2 74:12 101:22,23 128:15 <b>60</b> 102:13 139:11 <b>637</b> 101:25 102:14 <b>65</b> 11:12 <b>650</b> 6:23 11:20 102:14 <b>654</b> 23:22 <b>6th</b> 103:25 <hr/> <b>7</b> <b>7</b> 74:13 101:25	102:14 171:13 <b>70</b> 33:14 156:6 <b>705</b> 102:13 <b>713</b> 2:15 <b>727</b> 23:24 <b>728</b> 23:24 <b>729</b> 23:24 <b>740</b> 6:24 10:10,18 11:21 <b>77010</b> 2:14 <b>78701</b> 1:18 <b>7th</b> 10:18 101:25 <hr/> <b>8</b> <b>8</b> 9:25 <b>80</b> 70:2,9 76:13 139:11 <b>85</b> 70:9 <b>8th</b> 137:16 <hr/> <b>9</b> <b>9</b> 1:14 4:7 17:1,2,2 17:4 156:23 157:8 <b>90</b> 11:15,18 148:15 155:23 <b>92</b> 48:5 155:23 <b>9516206</b> 2:15		
<hr/> <b>3</b> <b>3</b> 3:13 6:12,13 10:9 10:16 16:6 23:22 90:23 98:21 118:10 177:8,10 <b>30</b> 27:19,20 <b>300</b> 143:7 148:23 <b>304</b> 2:7 <b>34</b> 17:2,4 <b>3441100</b> 2:7 <b>351</b> 23:12 <b>365</b> 102:10 <b>37</b> 3:15 <b>3d</b> 175:8 <hr/> <b>4</b>				